EXHIBIT C

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF SUFFOLK

IN RE OPIOID LITIGATION *This document relates to:* *The County of Suffolk, New York v. Purdue Pharma L.P.*, Case No. 400001/2017 *The County of Nassau, New York v. Purdue Pharma L.P.*, Case No. 400008/2017 *The People of the State of New York v. Purdue Pharma L.P.*, Case No. 400016/2018	Index No. 400000/2017 Motion Sequence Nos. 219, 220, 221, 222, 223, 224, 225, 226, 227 Hon. Jerry Garguilo

PLAINTIFFS' OMNIBUS RESPONSE TO THE DEFENDANTS' MOTIONS TO STRIKE OR EXCLUDE EXPERT WITNESSES

March 10, 2020

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INTRODUCTION

Defendants have filed a total of nine motions to exclude the testimony of Plaintiffs' expert witnesses. The witnesses that are the subject of these motions are: James Rafalski (Mot. Seq. 221), Craig McCann (Mot. Seq. 227), Lacey Keller (Mot. Seq. 223), Dr. Katherine Keyes (Mot. Seq. 220 and 224), Dr. Anna Lembke (Mot. Seq. 219 and 224)[1], Dr. David Kessler (Mot. Seq. 225), Dr. Marc Manseau (Mot. Seq. 226)[2], and Dr. James Tomarken (Mot. Seq. 222). Although Defendants purport to invoke the *Frye* standard as the primary basis (in many instances, the sole basis) for excluding the testimony of these experts, as discussed below, *Frye* applies only where an expert's testimony is based on novel scientific principles or procedures. Where an expert's opinion is in a field other than science, or where the basis of his or testimony is not a novel principle or procedure, *Frye* is simply inapplicable. All of Defendants' motions can be denied on this basis alone, as many of Plaintiffs' experts offer opinions in fields other than science, and even those whose opinions are grounded in science have not applied novel techniques, principles, or procedures to reach their conclusions.

Indeed, all of the experts at issue except Dr. Tomarken, who is the Suffolk County Commissioner of Health, were designated as experts for the MDL CT1a trial. The CT1 defendants moved to exclude their testimony under the more expansive federal *Daubert* standard, but with very limited exceptions those motions were denied. Judge Polster thoroughly considered the motions to exclude in advance of the CT1 October 2019 trial, and wrote lengthy opinions regarding each. For the Court's convenience, each of those orders is attached to the accompanying Affirmation of Justin Presnal ("Presnal Aff."). *See* Presnal Aff., Exhibit 1 (Opinion and Order Denying Motion to Exclude

[1] Defendants filed motions to exclude generally the testimony of Drs. Lembke and Keyes (Mot. Seq. Nos. 219 and 220), as well as a separate motion to exclude what they refer to as "marketing causation" opinions offered by these two witnesses (Mot. Seq. No. 224).

[2] Plaintiffs do not intend to call Dr. Manseau; the motion addressed to him is thus moot.

Keller, Dkt. 2492 (8/20/19); Exhibit 2 (Opinion and Order Regarding Defendants' Motions to Exclude Opinions of James Rafalski and Craig McCann, Dkt. 2494 (8/20/19); Exhibit 3 (Order regarding Defendants' Motion to Exclude Expert Testimony of Katherine Keyes, Anna Lembke, and Jonathan Gruber[3] regarding the "Gateway Hypothesis" of Causation, Dkt. 2518 (8/26/19); Exhibit 4 (Opinion and Order Granting in Part Defendants Motion to Exclude Marketing Causation Opinions of Schumacher,[4] Lembke, and Keyes, Dkt. 2549 (8/28/19); Exhibit 5 (Opinion and Order Granting in Part and Denying in Part Motion to Exclude Kessler and Perri,[5] Dkt. 2558 (9/3/19).

In sum, Judge Polster (applying the *Daubert* standard):

- Denied in total the defendants motion to exclude Lacey Keller (Presnal Aff., Ex. 1);
- Denied in total the defendants' motion to exclude Craig McCann (Presnal Aff., Ex. 2);
- Denied the defendants' motion to exclude James Rafalski, but held that Mr. Rafalski could not testify about (1) what the law required or whether the defendants violated the law, or (2) four specific opinions that were based on legal guidance from Drug Enforcement Agency attorneys that he could not disclose pursuant to *Touhy* regulations (Presnal Aff., Ex. 2);
- Denied in total the defendants' "gateway hypothesis" motion regarding Dr. Keyes and Dr. Lembke (Presnal Aff., Ex. 3);
- Denied the defendants' motion to exclude Dr. Kessler, noting that while "in general, no expert will be allowed at trial to offer legal opinions, to opine on whether a Defendant complied with the law, to offer lengthy narrative recitals of facts or of excerpts from documents, or to testify on what was a Defendant's state of mind," Kessler could "testify as to most if not virtually all of his specific opinions without crossing these boundaries." (Presnal Aff., Ex. 5 at 8).[6]
- With regard to defendants' marketing causation motion, held that "the Court will exclude the limited portions of their opinions that purport to find *causation* with respect

[3] Dr. Gruber was not designated as an expert by Plaintiffs in these cases.

[4] Dr. Schumacher was not designated as an expert by Plaintiffs in these cases.

[5] Dr. Perri was not designated as an expert by Plaintiffs in these cases.

[6] Judge Polster also precluded Dr. Kessler from offering testimony about J&J subsidiaries Noramco and Tasmanian Alkaloids, but on the sole basis that the opinions were not timely disclosed in his MDL expert report. *See* Presnal Aff., Ex. 5. Dr. Kessler's expert report in these cases includes full disclosure of his opinions with respect to Noramco and Tasmanian Alkaloids.

> to the effect that Defendants' marketing efforts had on increased sales and/or increased prescriptions of opioids. As discussed below, this ruling applies narrowly – that is, it excludes only to [sic] these witnesses' opinions regarding marketing causation and does not impact their remaining opinions in any way." (Presnal Aff., Ex. 4 at 2, emphasis in original).

As discussed below, with the exception of the "marketing causation" opinion, these opinions can and should be adopted and applied here. As to marketing causation, however, the opinions offered by Dr. Lembke and Dr. Keyes with respect to the relationship between Defendants' marketing and the prescribing practices of doctors are different from, and significantly enhanced in comparison with, the opinions that were the subject of Judge Polster's order on this topic. Thus, applying the analysis set forth in that opinion, and using the *Frye* standard applicable in New York, this Court can readily conclude that these opinions, like the remainder of the opinions offered by these witnesses, are admissible and should not be excluded. Defendants' motions should be denied in their entirety.

LEGAL STANDARD

The *Frye* standard only applies to novel scientific theories.

New York courts apply the standard set forth in *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923), to expert testimony involving novel scientific principles or procedures. *See Parker v. Mobil Oil Corp.*, 7 N.Y.3d 434, 446 (2006). If the expert testimony is not scientific, or if it does not rely on novel scientific principles, *Frye* does not apply. *See People v. Brooks*, 31 N.Y.3d 939, 941 (2018) ("Absent a novel or experimental scientific theory, a *Frye* hearing is generally unwarranted."); *Wahl v. Am. Honda Motor Co.*, 181 Misc. 2d 396, 398-99 (Sup. Ct., Suffolk County 1999) (when "evidence is not scientific or not novel, the *Frye* analysis is not applicable").[7]

[7] In this respect – among others – *Frye* differs from Federal Rule of Evidence 702 and the *Daubert* standard, which the U.S. Supreme Court has specifically found applicable to all expert testimony. *See Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 147-48 (1999). *Kumho Tire* is specifically grounded in the text of F.R.E. 702, *see* 526 U.S. at 147. New York has no comparable rule and, as discussed in the text, New York courts have never expanded *Frye* beyond its original context of novel scientific procedures. *See Parker*, 7 N.Y.3d at 446 (re-iterating use of *Frye* test for "novel scientific evidence").

Where *Frye* does apply, the party challenging the expert opinion bears the burden of making "a prima facie showing that it is a novel theory which is not generally accepted." *Santos v. State Farm Fire and Cas. Co.*, 28 Misc. 3d 1078, 1079 (Sup. Ct., Nassau County 2010). Once this initial burden is satisfied, "[t]he burden then shifts to the proponent of the evidence to show by a fair preponderance of the credible evidence that there is sufficient general acceptance of its reliability." *Id.* "General acceptance" does not require that the scientific theory be endorsed by all, or even a majority of, scientists. *See Ratner*, 91 A.D.3d at 71. It simply means "'that those espousing the theory or opinion have followed generally accepted scientific principles and methodology in evaluating [the] data to reach their conclusions.'" *Id.* (citation omitted). General acceptance can be established through a variety of sources, including scientific literature, judicial opinions, and expert testimony.

The *Frye* inquiry focuses on "the basis for the expert's opinion and does not examine whether the expert's conclusion is sound." *Lugo v. New York City Health & Hosps. Corp.*, 89 A.D.3d 42, 56 (2d Dep't 2011). Thus, the *Frye* analysis is limited to the expert's procedure or methodology; courts are "not concerned with the reliability of a certain expert's conclusions[.]'" *Nonnon v. City of New York*, 32 A.D.3d 91, 103 (1st Dept. 2006). It is the technique or procedure used that "must be sufficiently established to have gained general acceptance in the particular field to which it belongs," not the conclusion itself. *Parker,* 7 N.Y. 3d at 446-47. It is not the Court's job "to decide who is right and who is wrong, but rather to decide whether or not there is sufficient scientific support for the expert's theory." *Lugo*, 89 A.D.3d at Factual disagreements with the expert's opinion go to the weight of the opinion, not its admissibility. *See, e.g., Wesley*, 83 N.Y.2d at 427-28.

Expert testimony is admissible if the expert is qualified and the opinion is based on a proper foundation.

All expert testimony must satisfy the general admissibility standard for evidence, which requires there be a proper foundation for the expert's opinion. *See Brooks*, 31 N.Y.3d at 941. This inquiry focuses on "'the specific reliability of the procedures followed to generate the evidence

proffered and whether they establish a foundation for the reception of the evidence at trial[.]'" *Parker*, 7 N.Y.3d at 447 (quoting *Wesley*, 83 N.Y.2d at 429). Expert testimony is based on a proper foundation if the expert "followed generally accepted methods for the collection and analysis of evidence and applied proper techniques to reach [his] conclusions." *Nonnon v. City of New York*, 32 A.D.3d 91, 104 (1st Dept. 2006), *aff'd*, 9 N.Y.3d 825 (2007). Any factual disagreements regarding the ultimate merit of the expert's opinion, or the validity of the evidence on which the expert relied, go to the weight of the opinion, not its admissibility. *See id.* at 108; *Wesley*, 83 N.Y.2d at 425; *Lugo*, 89 A.D.3d at 63.

The expert also must be "possessed of the requisite skill, training, education, knowledge or experience from which it can be assumed that the information imparted or the opinion rendered is reliable." *Matott v. Ward*, 48 N.Y.2d 455, 459 (1979). However, the expert "need not be a specialist in the particular area at issue to offer an opinion. Any lack of skill or expertise goes to the weight of his or her opinion as evidence, not its admissibility." *Leavy v. Merriam*, 133 A.D.3d 636, 638 (2d Dept. 2015) (internal citations omitted); *see also Adamy v. Ziriakus*, 92 N.Y.2d 396, 402 (1998) (challenges to credentials "affect the weight to be accorded [the expert's] views, not their admissibility"); *Ariola v. Long*, 197 A.D.2d 605, 605 (2d Dept. 1993).

ARGUMENT

I. This Court should not exclude the testimony of Rafalski, McCann, and Keller pertaining to Defendants' Suspicious Order Monitoring Systems ("SOMs")

Defendants seek to exclude testimony of three experts who offer opinions about Defendants' SOMs programs, and whose opinions are inter-related. The three experts are (1) James Rafalski, a former DEA agent, who provides background and context concerning Defendants' SOMs obligations under the CSA, offers opinions about the components of an appropriate SOMs program, and identifies five methods that a distributor could use to identify "suspicious orders" as that term is used under the CSA; (2) Dr. Craig McCann, an economist with significant expertise in data analysis and computation, who applied the five metrics identified by Rafalski to ARCOS data collected by the DEA

from distributors of controlled substances, to determine the number of orders shipped by Defendants that would have been flagged under these various metrics; and (3) Lacey Keller, a data mining expert who similarly applied various SOMs metrics, including those identified by Rafalski, to several data sets, including ARCOS data and "IQVIA" data, which reflects prescriptions filled at pharmacies throughout New York (and in particular on Long Island).

Keller and Dr. McCann each found millions of opioid shipments to New York that would have been flagged under the various metrics that could have been used to identify suspicious orders or problematic prescribing, but that Defendants nonetheless failed to halt and failed to identify as possible or probable sources of diversion. All three of these experts offered similar opinions in the MDL, and motions to exclude their testimony in the CT1 trial were denied by Judge Polster.

Rafalski, McCann, and Keller should similarly all be permitted to testify here. As discussed below, all three are fully qualified to offer their opinions. None of the opinions are scientific and none depend on novel procedures. Rather, Rafalski's opinions are based on his experience in law enforcement and, in particular, with the DEA, while McCann and Keller use math – addition, subtraction, multiplication, and division – to analyze reliable, but complex sets of data. Defendants' quarrels with the assumptions used by McCann and Keller in making their computations are fodder for cross-examination, but provide no basis on which the exclude the opinions of any of them.

A. Rafalski, McCann, and Keller offer opinions relevant to Defendants' compliance with the CSA

As set forth in Plaintiffs' Memorandum of Law in Support of Motion for Partial Summary Judgment Concerning Defendants' Statutory and Regulatory Duties [NYSCEF Doc. No. 2849] ("Pltf. SOMs Br."), all of the Defendants – Manufacturers, Distributors, and Pharmacy Chains – are subject to regulation under the federal Controlled Substances Act, 21 U.S.C. §§ 801 et seq. ("CSA") and the New York Controlled Substances Act, Pub. Health Law § 3312 ("NYCSA"). The CSA and NYCSA both require manufacturers and distributors to maintain "effective controls against diversion." Pltf.

SOMs Brief at 1, *citing* 21 U.S.C. § 823, and N.Y. Pub. Health Law § 3312. Regulations promulgated by the DEA require manufacturers and distributors to design and operate a system for identifying and reporting suspicious orders. *Id.*, and at 4-5 (*citing* 21 C.F.R. § 1301.74). Those regulations define suspicious orders to include "orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." *Id.*

The CSA and the NYCSA establish a "closed system" for the manufacture, sale, and distribution of prescription opioids. In order to maintain this "closed system" (and in exchange for the privilege of dealing in controlled substances), Defendants are required to maintain "effective controls against diversion." *See Masters Pharm., Inc. v. DEA.*, 861 F.3d 206, 212-213 (D.C. Cir. 2017); *Southwood Pharm., Inc.; Revocation of Registration*, 72 FR 36487-01, 36500, 2007 WL 1886484 (DEA July 3, 2007). They must (i) design and operate a system to identify suspicious orders; (ii) report to the DEA suspicious orders "when discovered"; and (iii) decline to ship an order identified as suspicious unless, through due diligence, they are able to determine that the suspicious order is not likely to be diverted. *See Masters Pharm.*, 861 F.3d at 212-213; *Southwood Pharm.*, 72 FR 36487-01, 36500; 21 C.F.R. § 1301.74. "Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. § 1301.74(b).

Defendants had a wealth of data available to them to assist them in identifying orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency. That data gave Defendants nearly complete visibility about the supply chain for their opioids, information that they could have used – but for the most part failed to use – to assist them in maintaining effective controls against diversion. As a former DEA agent, Rafalski offers opinions about how Defendants might have used this data to comply with their statutory and regulatory obligations. Relying on information from Rafalski, McCann and Keller have done what Defendants

willfully or negligently failed to do: they analyzed the relevant data. Their analysis will allow the fact-finder to see what Defendants would have seen if they had only looked.

The results of the McCann and Keller analyses are stark: they show that with consistent use of such metrics, Defendants could have detected millions of pharmacy purchases or prescriptions with indicia of problematic prescribing or suspicious purchasing patterns, including orders of unusual size, frequency, or pattern. The results of these analyses demonstrate that Defendants' failure to maintain appropriate SOMs programs was not merely a technical violation of the CSA and the NYCSA, but rather resulted in the shipment of millions of dosage units of opioids that would have been flagged as suspicious, and could have been stopped, had Defendants carried out their obligations to detect, identify, report, and halt suspicious orders and illegitimate prescriptions.

B. Rafalski, McCann, and Keller are qualified to offer their opinions.

Mr. Rafalski's background and experience are described in Judge Polster's order, as well as in his report. *See* Presnal Aff., Ex. 2 at 2-4; *see also* Defs. Rafalski Mot. Ex. 2 at 7-10 ("Rafalski Report"). He spent 26 years as a law enforcement officer, then joined the DEA in 2004 as a Diversion Investigator for the Detroit Divisional Office. He served in that role until his retirement in 2017, and was "responsible for conducting regulatory, state, civil, administrative, and criminal investigations." *Id.* "[H]e investigated the criminal conduct of individual physicians regarding improper opioid prescriptions and conducted regulatory investigations involving, inter alia, Distributors' compliance with DEA requirements regarding suspicious order monitoring systems ('SOMSs')." *Id.* Judge Polster's order describes three significant investigations conducted by Mr. Rafalski that specifically involved the evaluation of distributor SOMS and identification of inadequate systems and conduct by distributors to "avoid triggering the company's SOMS." Presnal Aff., Ex. 2 at 2-4. His investigation of Masters Pharmaceutical from 2010 to 2013, which involved examination of the company's due diligence records and SOMS information, resulted in the DEA revoking the company's license to

manufacture or distribute controlled substances. *Id.* at 3, citing *Masters Pharm., Inc. v. DEA*, 861 F.3d 206 (D.C. Cir. 2017) (cited and discussed in Pltfs. SOMs Brf., NYSCEF 2849, at 1-2, 4-5). As the MDL court noted, "[a]s a former Diversion Investigator, Rafalski clearly has experience and expertise regarding the components of and characteristics he would expect to be included in an effective SOMS and due diligence program." Presnal Aff., Ex. 2 at 8.

Dr. McCann is a data computation and analysis expert. He has over 25 years of experience receiving and extracting data, processing and validating data, and producing various statistical analyses. Report of Craig McCann, NYSCEF 5211. He has served as an expert or consultant in over 100 different cases. *Id.* at 97-107. He is the President of the Securities Litigation and Consulting Group ("SLCG") which was founded in 2000 to apply finance, economics, statistics and mathematics in litigation and consulting. Dr. McCann earned his Ph.D. in economics from the University of California at Los Angeles. There is no doubt that Dr. McCann is qualified to perform he data analysis that underlies his expert report and the opinions he intends to offer at trial.

Lacey Keller is similarly qualified to offer her opinions. She holds a Masters of Economics degree from the New School for Social Research, a Bachelor of Business Administration degree from Washburn University, and a Certificate in Data Science from General Assembly. She is the Managing Director for Data Mining & Analytics with Gryphon Strategies, Inc., a leading investigation firm, where she created and directs their data mining and analytics division. In her current role, she advises financial and law firms on the use of data for investments and investigations. Prior to founding Gryphon's Data Mining & Analytics Division, she founded and directed the Research and Analytics Department for the New York State Office of the Attorney General ("NYAG"), where she served from 2013 to 2017. Keller's primary role at the NYAG's office was to help the office identify areas for investigation using data. In this role, she was frequently asked to investigate subject areas in which she had no prior expertise. To accomplish such assignments, Keller educated herself on the subject

areas through research and discussions with subject matter experts. Included among such assignments was extensive work on issues related to opioids. For example, while at the NYAG, she developed and managed the Community Overdose Prevention Program, which uses data analytics to determine how best to deploy life-saving naloxone across New York State. Chief among the datasets she used for opioids-related work was the DEA's public ARCOS data. *See, generally*, Keller Report, NYSCEF No. 5210

Neither McCann nor Keller claims to be an expert in SOMs compliance. They offer no opinion on whether the orders flagged by their analysis were actually "suspicious" within the meaning of the applicable regulations. Rather, they are computational and data mining experts who have marshaled the relevant data and applied appropriate metrics to determine whether the metrics flagged the transactions to which they were applied. Contrary to Defendants' suggestion, a data mining expert "need not … have direct experience with the precise subject matter or product at issue." *Jackson v. E-Z-GO Div. of Textron, Inc.*, 326 F. Supp. 3d 375, 388 (W.D. Ky. 2018) (electrical engineer's "knowledge and experience qualify him to be able to offer opinions on regenerative braking" despite lack of specific experience with that type of technology); *Laski v. Bellwood*, 132 F.3d 33 (6th Cir. 1997) (district court abused discretion excluding testimony of causation experts who were "only" medical specialists and not experts in biomechanics or accident reconstruction because "[r]equiring such specialization thwarts the goals and purposes of the Federal Rules", citing *DaSilva v. American Brands, Inc.*, 845 F.2d 356, 361 (1st Cir. 1988) (trial court properly permitted mechanical engineer to give an opinion on the safety of the design of an industrial mixing machine even though the witness had no design experience with the particular machine at issue). It is thus of no moment that Keller and McCann offer no opinion on the question whether particular orders were "suspicious" as that term is defined in the governing regulation. An expert is not required to "know answers to all the questions a case presents." *Jahn v. Equine Servs., PSC*, 233 F.3d 382, 390 (6th Cir. 2000). Their analyses will help the fact-finder

understand what would have happened if Defendants had applied any of the various metrics to the data they had available. Defendants do not suggest that the fact-finder would be competent to perform anything like the enormous "number crunching" exercise performed by McCann or Keller.

C. Rafalski's opinions should not be excluded

In order to exclude Rafalski's opinions, Defendants must show either that they are based on novel scientific procedures and thus are subject to the *Frye* analysis, or that they otherwise lack a sufficient foundation to be admitted into evidence. They can show neither. Instead, the primary focus of Defendants' attack is certain new paragraphs that were added to the report submitted in these cases but were not included in his MDL report. As discussed below, however, the new information is virtually all factual in nature, simply providing additional factual bases for opinions that are very similar to the ones offered the MDL, but with respect to Suffolk and Nassau Counties, and New York state, rather than the CT1 Ohio counties.

1. Rafalski's opinions do not employ novel scientific techniques

Defendants argue that Mr. Rafalski's methodology for analyzing their SOMs programs is not "generally accepted," and is thus inadmissible under *Frye*. But as discussed above, the *Frye* standard only applies to "novel scientific" evidence, not the type of evidence Mr. Rafalski will offer.

As summarized his Report, Rafalski offers the opinion that

> each and every one of the pharmaceutical distributors and manufacturers at issue here, both on a nationwide basis and specifically within New York State and Suffolk and Nassau Counties:
>
> > (i) failed, in a systematic, widespread, and prolonged manner, to maintain effective controls to prevent diversion;
> >
> > (ii) failed, in a systematic, widespread, and prolonged manner, to design and operate effective systems to monitor suspicious orders;
> >
> > (iii) engaged in a systematic, widespread, and prolonged pattern of failing to identify and report thousands of specifically-identifiable, suspicious orders for opioids;

> (iv) engaged in a systematic, widespread, and prolonged pattern of failing to prevent shipment and sale of thousands of specifically-identifiable, suspicious orders for opioids.
>
> It is also my opinion that the analytical methodologies that I identify herein are appropriate methodologies, some of which were utilized by the Defendants in one format or another, for identifying groups of suspicious orders of opioids that the distributors and manufacturers failed to block from delivery to customers across the country, including in New York.
>
> It is also my opinion that as a functional and practical matter, within the closed-loop regulatory mechanism governing controlled substances, the development or persistence of any single one of the above-identified conditions within a nationwide distributor or manufacturer of controlled substances would likely result in that company's constructive abandonment of its role within the wider regulatory mechanism governing controlled substances, and it is further my opinion that such constructive abandonment by any such key market participant would likely result in the entire wider regulatory mechanism being critically undermined during the period of such abandonment and for at least a substantial period of time thereafter.
>
> Finally, it is also my opinion that as a functional and practical matter, within the closed-loop regulatory mechanism governing controlled substances, any distributor or manufacturer that allowed any single one of the above-identified conditions to develop or persist within the company could only have done so in conscious disregard of basic and readily-available information about the company's own controlled-substance activities and the grave risks to public health and order that they posed.

Rafalski Report, NYSCEF No. 5214 at 5-6, 159-160.[8]

None of these opinions is "scientific" and none depends on novel procedures of any kind. Rather, Rafalski has applied his experience as a DEA agent to identify a range of appropriate SOMs metrics, and to assess the results of Defendants' programs, as reflected in the data showing the orders they shipped to New York. *Frye* is thus inapplicable, and this Court need only determine that Mr. Rafalski's opinions are based on a substantial factual foundation.

[8] These are substantively the same opinions Mr. Rafalski offered in the MDL CT1a litigation, which Judge Polster concluded were reliable and would be helpful to the jury.

2. Rafalski's methodology for examining the Defendants' SOMs is the same one he used when he was conducting investigations for the DEA, and it is both reliable and well-founded.

Mr. Rafalski identified five different methodologies for identifying suspicious orders. Those methodologies were applied to data from the DEA's ARCOS database in order to determine the extent to which Defendants' shipments of opioids should have been identified as potentially "suspicious." He found that "[e]ach method would have identified a significant volume of orders of opiates" that were suspicious and should not have been shipped unless a due diligence review concluded that the order was appropriate. Rafalski Report, NYSCEF No. 5214, at 45.

The Defendants take issue with the five methodologies, but the MDL court specifically held "[b]ased on Rafalski's extensive field experience as a DEA investigator reviewing the effectiveness of Distributors' SOMS, the Court finds his expertise in identifying methodologies available to flag potentially suspicious orders is reliable." Presnal Aff., Ex. 2 at 12. Moreover, some of the methodologies used by Mr. Rafalski were used by some of the Defendants in their own SOMs. Rafalski Report, NYSCEF No. 5214, at 45. As Defendants note in their brief, Mr. Rafalski testified that he viewed the "Maximum Monthly, Trailing 6 Month Threshold" methodology as the best suited for identifying potentially suspicious orders. *See* Def. Rafalski Brief at 14. Defendants argue that this methodology is not "generally accepted" because none of them used it, but it was specifically endorsed by the D.C. Circuit in *Masters*. 861 F.3d at 216-217 ("As a matter of common sense and ordinary language, orders that deviate from a six-month trend are an 'unusual' and not 'normal' occurrence."); *see also* Presnal Aff., Ex. 2 at 11-12 (citing *Masters*).

Mr. Rafalski should be permitted to testify about *all* of the methodologies he identified in his report, because it will help the jury resolve the issues to be decided in this case. As the MDL court observed,

> in determining whether Defendants employed effective measures to identify, investigate, and stop shipments of suspicious orders, it would be helpful to the finder

> of fact to hear evidence about the number of suspicious orders that each methodology would have flagged. Accordingly, the Court concludes that Rafalski's methodologies are reliable and would aid the jury's determination of material issues in the case.

Presnal Aff., Ex. 2. Defendants are free, of course, to cross-examine Mr. Rafalski at trial about any limitations or criticisms they have of his methodologies, which would go to the weight to be afforded Mr. Rafalski's opinions, not their admissibility.

Finally, Defendants' argue that Mr. Rafalski's opinions should be excluded because he improperly concluded that, once an order is flagged as suspicious, then all subsequent orders from that same purchaser would also be suspicious and should not be shipped until a due diligence review is completed. Def. Rafalski Brief at 15-16. However, as discussed below (with respect to Lacey Keller) this approach acknowledges the "real world" problem with suspicious orders: once an order is identified as suspicious, no other orders should be shipped until a due diligence review is completed. *See also* Presnal Aff., Exhibit 2 at 13 (finding Rafalski's opinions "provide relevant evidence regarding whether Defendants maintained effective control against diversion including whether they adequately identified, investigated, and/or stopped shipment of suspicious orders.")

3. The new material in Rafalski's report is virtually all facts, not opinions, so Defendants' complaints about the new material are irrelevant, and certainly do not justify exclusion.

The Defendants devote approximately half of their brief complaining about additions to Mr. Rafalski's report, suggesting that those additions were improper and not fully vetted by Mr. Rafalski. They prepared a seventy page chart with screenshots of the new additions. (Rafalski Mot. Ex. 1). Those complaints are both misguided and irrelevant.

First, as a review of the Defendants' chart shows, the new material is virtually all *factual* in nature. Those additional facts did not cause Mr. Rafalski's *opinions* to change, they merely provide additional *factual* support for the opinions he intends to express – which are the same opinions he expressed in his MDL report. That these additional factual basis align with Plaintiffs' allegations is no ground for excluding Mr. Rafalski's opinions. Indeed, Plaintiffs must prove the factual predicates of

their case in order to prevail in any event. That Mr. Rafalski viewed Plaintiffs' allegations as providing additional support for his opinions does not in any way undermine the foundation of those opinions.

Nor was there anything improper about the process by which these factual matters were included in his report: as Mr. Rafalski testified, he worked with the lawyers who provided factual information, reviewed the information they provided, and determined what would, and would not, be included in his report. Rafalski 2/7/2020 Dep., at 495-97 (Rafalski Mot. Ex. 4). Although he did not himself insert the material into the report, he testified that he reviewed the material supplied by Plaintiffs' counsel and the footnotes that supported it. *Id.* There is nothing wrong or improper about this practice; lawyers routinely provide expert witnesses with discovery materials they have obtained during the course of litigation that demonstrate the facts upon which experts rely in forming their opinions. *See, e.g.*, 4 N.Y.PRAC., COM. LITIG. IN NEW YORK STATE COURTS § 30:7 (4th ed.) ("As a general rule, the attorney should provide the expert with all the facts that the expert requests in order to formulate opinions, as well as any facts that the lawyer anticipates becoming a subject for cross-examination."). Mr. Rafalski's testimony that he could have missed "one or two" footnotes in reviewing the material provided by the lawyers, Rafalski 2/7/2020 Dep., at 497 (Rafalski Mot. Ex. 4), in no way undermines the use of this material in his report.

Moreover, despite Defendants' complaints about the form of Mr. Rafalski's report, preclusion of expert testimony is considered a "drastic" remedy. *See Prasad v. B.K. Chevrolet, Inc.*, 184 A.D.2d 626, 627 (2d Dept. 1992); *Teachers Ins. and Annuity Ass'n of Am. v. Coopers & Lybrand*, 183 A.D.2d 473, 474 (1st Dept. 1992). Preclusion based on deficiencies in an expert's disclosures is typically only granted when an expert's opinions are not timely disclosed, and even then New York courts regularly refuse to impose such harsh relief unless the circumstances are particularly egregious.[9] *See, e.g., Rivera v. New*

[9] This Court already considered, and rejected, a motion by the Defendants to strike Mr. Rafalski's report as untimely, concluding that striking the report "is too drastic a remedy." NYSCEF No. 3161. Consequently,

York City Hous. Auth., 177 A.D.3d 499, 499-500 (1st Dept. 2019) (defendant failed to show it was prejudiced by untimely disclosure of plaintiff's expert, and thus preclusion of expert evidence was not warranted, where plaintiff disclosed expert approximately six weeks before originally-scheduled trial date and expert "did not advance a different theory of liability from that which plaintiff had previously advanced"); *Silverberg v. Community Gen. Hosp. of Sullivan County*, 290 A.D.2d 788, 789 (3d Dept. 2002) (preclusion of expert testimony based on plaintiff's two-year delay in identifying experts not warranted where there was no evidence the failure to disclose was willful or intentional, was unreasonable under the circumstances, or that it caused prejudice to defendants); *Madison 96th Assoc., LLC v. 17 E. 96th Owners Corp.*, 2016 N.Y. Slip Op. 30383(U), 2016 WL 951518, at *9-10 (N.Y. Sup. Ct., New York County 2016) (plaintiff precluded from offering expert evidence on diminution in building's value "because it ha[d] not shown good cause for failing to disclose an expert or other discovery on this issue. . . . during twelve years of litigation"); *Keyspan Gas E. Corp. v. Munich Reins. Am., Inc.*, 2016 N.Y. Slip Op. 31185(U), 2016 WL 1258500, at *2 (N.Y. Sup. Ct., New York County 2016) (excluding testimony of defendant's expert where (i) defendant did not disclose the expert until two years after the close of expert discovery and failed to offer any explanation for the delay, and (ii) the expert's opinion was not only entirely new, it contradicted the position defendant had previously taken during the litigation).

There is no question that Defendants were made fully aware of Mr. Rafalski's opinions and the facts upon which those opinions were based: in addition to his 160+ page report, the Defendants were permitted to conduct 14 hours of deposition questioning of Mr. Rafalski, a deposition that is more than 1,000 pages in length. *See* Rafalski Mot. Ex. 4, 5. Any issues Defendants have with the inclusion of additional factual material in the Rafalski Report can be taken up in cross-examination.

Defendants' discussion about the sequence of events leading up to the production of Mr. Rafalski's report are irrelevant and should be disregarded.

D. The Court should not exclude the opinions of data analyst and computational expert Dr. Craig McCann.

Dr. McCann used the five metrics identified by Rafalski, and analyzed the ARCOS data under each of them. His analysis shows that hundreds of thousands of dosage units of opioids were shipped to each of Nassau and Suffolk Counties as part of orders that would have been flagged as "suspicious" had Defendants applied these metrics. Dr. McCann also reviewed the ARCOS data for its reliability, and determined that the ARCOS Data as provided by the DEA is "complete and reliable" and that it "can be used to identify transactions into a state, county, zip code or individual pharmacy meeting certain criteria." McCann Report, NYSCEF No. 5211, at 62.

The bulk of Defendants' challenges to Dr. McCann's opinions do not actually address Dr. McCann's calculations and opinions, but rather simply repeat Defendants' attacks on Mr. Rafalski's methodology. It is Mr. Rafalski, with his DEA expertise, who identified the appropriate SOMS metrics for Dr. McCann to analyze, and it is Mr. Rafalski, again based on his DEA expertise, who assessed the result of Dr. McCann's analysis. Dr. McCann's role is limited and straightforward: he has the data analysis expertise to apply the metrics identified by Mr. Rafalski to the available data. Defendants offer no serious critique to the computations Dr. McCann made.

1. Dr. McCann's mathematical analysis is not novel science and is not subject to Frye

Dr. McCann's expert opinion is limited to "cleaning the [ARCOS] data and reporting the results of [ ] arithmetic."[10] Dr. McCann is not being offered as an expert in suspicious order monitoring and takes no position on whether the assumptions used in his report are appropriate; rather he simply opines that applying the algorithms or formulas identified by Mr. Rafalski to the ARCOS data produces the results outlined in his report.[11] Indeed, approximately 90 percent of the

[10] Presnal Aff., Ex. 6, NY Deposition of Craig McCann ("McCann NY Dep. Tr.") 108:23-25.

[11] Presnal Aff., Ex. 7, MDL Deposition of Craig McCann ("McCann MDL Dep. Tr.") 129:2-15.

McCann report is simply "descriptive statistics."[12] The methods of calculation in the five metrics Dr. McCann used "have been around for millennia; it's addition, subtraction, multiplication and division."[13] Dr. McCann's analysis, put simply, is "just complicated arithmetic applied to a very large data set."[14]

Such basic mathematical calculations are not "novel science" and not properly subject to *Frye* analysis. Where a methodology, like Dr. McCann's, "does not rely on the application of scientific principles but incorporates basic math with the observations and experience of the valuators," the methodology "does not constitute scientific evidence subject to a *Frye* hearing." *In re Marriage of Alexander*, 368 Ill App. 3d 192, 201, 857 NE2d 766, 773 (Ill App Ct 2006) (holding "addition, multiplication, and division[] are certainly not novel… although certainly some are more versed at applying them than others" and not subject to *Frye*). *Accord People v Reynolds*, 193 Misc. 2d 697, 705-06 [NY Co Ct 2002], *affd*, 307 AD2d 391 [3d Dept 2003] ("[A] *Frye* hearing is not required … [where the opinions and testimony are] based upon the laws of physics and mathematical calculations neither of which are "novel".).

That the Defendants disagree with the application of these basic mathematical methodologies as part of this particular inquiry does not preclude Dr. McCann's analysis. *See People v. Debraux*, 50 Misc. 3d 247, 255–58, 21 N.Y.S.3d 535, 542–44 (N.Y. Sup. Ct. 2015) ("evidence derived from the application of a generally accepted technique, even if the application was unique or modified in a particular case, is admissible without the need for a Frye hearing").

Further, even if *Frye* analysis were applied to such mathematical formulas, "the evidence would pass the general-acceptance test because elementary mathematics has gained general acceptance in all

[12] Presnal Aff., Ex. 7, 469:24-470:1-6.

[13] *Id.* at 472:14-21.

[14] *Id.* at 471:10-13.

fields of science and engineering." *Id.* at 518. Mathematics in general and data mining in particular are generally accepted in the scientific community: "Deduction, extrapolation, drawing inferences from existing data, and analysis are not novel methodologies and are accepted stages of the scientific process." *Ratner v McNeil-PPC, Inc.*, 91 AD3d 63, 74 (2d Dept. 2011). Indeed, data mining is routinely used both in the pharmaceutical industry and among regulators worldwide. *See In re Abilify (Aripiprazole) Prod. Liab. Litig.*, 299 F. Supp. 3d 1291, 1316 (N.D. Fla. 2018); *Rheinfrank v. Abbott Labs., Inc.*, No. 1:13-cv-144, 2015 WL 13022172, *13 (S.D. Ohio Oct. 2, 2015); *In re Fosamax (Alendronate Sodium) Prod. Liab. Litig.*, Nos. 11-5304, 08-08, 2013 WL 1558690, *8 (D.N.J. Apr. 10, 2013); *In re Yasmin and YAZ (Drospirenone) Mktg., Sales Practices and Prod. Liab. Litig.*, No. 3:09–m.

2. *Dr. McCann properly applied Mr. Rafalski's methodologies.*

Defendants offer three specific criticisms of Dr. McCann's report. None provides a basis to limit or exclude his testimony:

Specific methodologies: Defendants contend that four of the methodologies Dr. McCann used were inappropriate and were not endorsed by Mr. Rafalski. This is not so. Mr. Rafalski explains that all five of the methodologies are meant to approximate tests the Defendants themselves endorsed or used and that Methodology A, which Mr. Rafalski testified would be being appropriate for flagging orders by size, was meant to reflect a test deemed appropriate for that purpose by the DEA and the courts. Dr. McCann applied all five calculations and provided the results of each.

Assumptions. Defendants take issue with the assumptions made by Dr. McCann, as directed by Plaintiffs' counsel and by Mr. Rafalski's report, and with the fact that Dr. McCann and Mr. Rafalski did not specifically discuss those assumptions in the course of producing Dr. McCann's report in this case. Dr. McCann's assumptions here are substantially identical to those he made in as part of his analysis of the ARCOS data in the MDL, where he applied substantially identical tests outlined by Mr. Rafalski in his MDL expert report. Defendants made substantially similar objections in the MDL to

those raised here, all of which were overruled by Judge Polster, who allowed both Dr. McCann and Mr. Rafalski's opinions to go forward to the fact finder. *See* Presnal Aff., Ex. 2. Though the MDL court employed the *Daubert* standard, that prior analysis and approval are instructive here. *See People v. Debraux*, 50 Misc. 3d 247, 255–58, 21 N.Y.S.3d 535, 542–44 (N.Y. Sup. Ct. 2015) ("[F]or purposes of *Frye* analysis, a court may rely upon "previous rulings in other court proceedings as aid in determining" whether a technique has been generally accepted and whether evidence generated by use of that technique is admissible."). Nor was it necessary for Dr. McCann and Mr. Rafalski to discuss these assumptions, or for Mr. Rafalski to review Dr. McCann's work. As Mr. Rafalski testified, he did not check Dr. McCann's mathematical calculations because Mr. Rafalski is "not a statistician of the caliber of Dr. McCann" and would not "have the ability to run the same analysis." *See* Rafalski Dep. at 910:8-13 (Rafalski Mot. Ex. 5).

Purported Errors in Report. Defendants further argue that Dr. McCann's inclusion of certain pharmacy data constituted "double counting" and was therefore erroneous. Defendants' characterizations are incorrect. Dr. McCann did not "double count," but provided multiple different calculations and ways of analyzing the data. These different methods were not aggregated, but rather, are transparent and each one stands on its own. To the extent Defendants argue inclusion of certain data in some of the calculations was erroneous, these "errors" do not invalidate Dr. McCann's opinions, testimony, or methodology under *Frye*. *See People v Belle*, 47 Misc. 3d 1218(A) (Sup Ct 2015) ("[A]n error in calculation [] that does not make the formula invalid … [and] has nothing to do with the *Frye* test for admissibility."). Though during the course of Defendants' near 14-hour questioning of Mr. Rafalski, certain limited calculations were taken out of context, Plaintiffs' subsequent examination put the numbers into their proper context and demonstrated their relevancy. *See e.g.* Rafalski Dep at pp. 964-972 (Rafalski Mot. Ex. 5). Defendants' suggestion that the Court disregard

Mr. Rafalski's clarifying testimony because it contradicts the point they wish to make should be rejected.

Persistent flagging: Defendants also criticize Dr. McCann's use of a persistent flagging approach as part of his calculations. With the persistent approach, after a metric flagged a pharmacy or prescriber for a given drug, all subsequent prescriptions for that drug would also be flagged. This approach is based on the reasonable assumption that once a pharmacy or prescriber has been flagged by a suspicious order monitoring system, the pharmacy or prescriber should remain flagged (*i.e.*, that all of its orders, or all of his or her prescriptions, for that drug should be treated as suspicious) until the defendant performs due diligence and establishes that the orders or prescriptions are not likely to be diverted.[15]

Not only is the persistent approach reasonable, Defendants' criticism of it provides no basis to exclude Dr. McCann's testimony. It is Mr. Rafalski, with his DEA experience, who provides the basis for using the persistent approach. As discussed above it was an appropriate assumption for Mr. Rafalski to utilize, and thus appropriate for McCann to use. Defendants are, of course, free to argue to the jury that persistent flagging is not an appropriate approach to calculating the number of suspicious orders they shipped to New York, but Mr. Rafalski provides support for Dr. McCann's use of it, and Dr. McCann's methodology in making the computation is sound and should not be excluded.

3. Dr. McCann's analysis is clearly relevant and will assist the trier of fact.

Defendants argue that because there was no legal requirement to use Methodology A, this methodology cannot be used to identify suspicious orders that Defendants were required to report (and halt), and hence Dr. McCann's analysis is "completely irrelevant." McCann Mot., NYSCEF No. 4421, at 13. But the fact that a Defendant could have used an alternative to Methodology A does not

[15] This assumption is also endorsed by Mr. Rafalski, as discussed above, and was one of the methodologies used by Lacey Keller.

render Methodology A unreliable for estimating the magnitude of suspicious orders that any reliable SOMS would have identified. As explained above, Mr. Rafalski utilized the same methodology considered and endorsed by the D.C. Circuit Court of Appeals in *Masters*. 861 F.3d at 216-217 ("As a matter of common sense and ordinary language, orders that deviate from a six-month trend are an 'unusual' and not 'normal' occurrence.")

Moreover, Defendants are wrong when they argue that because Dr. McCann does not offer an opinion as to whether the orders flagged by the mathematical calculations are truly suspicious, that his analysis is irrelevant to causation. McCann Mot., NYSCEF No. 4421 at 15. To the contrary, as set forth in Plf. SOMs Br., NYSCEF No. 2849, DEA regulations require that, in order to maintain effective controls against diversion, a registrant must design and operate a system to identify suspicious orders of controlled substances (the "identification duty"); report to the DEA suspicious orders "when discovered" (the "reporting duty"); and decline to ship an order identified as suspicious unless, through due diligence, the registrant is able to determine that the order is not likely to be diverted into illegal channels (the "no-shipping duty"). Mr. Rafalski's report sets forth his opinion that Defendants violated all of these duties: they failed to maintain adequate SOMs to identify suspicious orders; they failed to conduct adequate due diligence on orders that should have been flagged as suspicious; and they shipped these orders notwithstanding the lack of due diligence. Dr. McCann's analysis establishes that these failures were not merely hypothetical, that in fact they resulted in tens (it not hundreds) of thousands of orders that could have been flagged as suspicious being shipped into New York and into Suffolk and Nassau Counties.

In short, Dr. McCann's analysis is clearly relevant to establishing the magnitude of Defendants' wrongful conduct and the harm it caused. Dr. McCann's data analysis provides an estimate of the number of suspicious orders that Defendants would have identified had they employed any of the

methodologies. Dr. McCann's expert report provides an estimate of the magnitude of Defendants' breach of their duties is part of Plaintiffs' overall framework of causation in this case.

E. Keller's opinions should not be excluded

Like Dr. McCann, Keller applied a series of metrics or algorithms to data reflecting Defendants' shipments and sales, in order to determine the quantity of opioids that would have been flagged as "suspicious" had Defendants used metrics like these to meet their SOMs obligations.

As they do here, Defendants sought to exclude Keller's testimony in the MDL, but Judge Polster held that her expert opinions were admissible:

> Keller's opinions regarding the metrics available to the Manufacturers and her application of these metrics to the Keller Data is relevant and helpful to the trier of fact. For example, her testimony will assist the jury in deciding: (1) whether Manufacturers employed reasonable measures to identify potentially suspicious orders; and (2) the number of orders Manufacturers could have flagged if they had employed these measures.

In re Nat'l Prescription Opiate Litig., No. 1:17-MD-2804, 2019 WL 3934470, at *7 (N.D. Ohio Aug. 20, 2019) (Presnal Aff., Ex. 1). As described below, this Court should reach the same conclusion.

1. Keller's opinions are not based on novel scientific techniques

As is true with both Rafalski and McCann, the *Frye* analysis is inapplicable to Keller's opinions, because she did use novel scientific techniques or procedures. Like McCann's, her methodology, while highly sophisticated, is "[j]ust math." Keller Dep. Tr. at 44:4 (Defs. Keller Brief Ex. 1).[16]

Keller's work is similar to McCann's, but involves multiple datasets and algorithms. Keller used ten different metrics, all of which were either identified by Rafalski or the court in the *Masters* decision, or were used by one of the Defendants. Keller applied these metrics to multiple data sets. First, Keller analyzed IQVIA Xponent data, which provides a representative sample of opioid

[16] There is no current NYSCEF number for this exhibit, since it was served under seal, as was Defendants' memorandum in support of their motion to exclude Keller. The Keller deposition transcript is attached as Exhibit 1 to the Defendants' memorandum.

prescriptions filled, including the doctor who wrote the prescription and the drug prescribed. This data was available to the Defendants; many of them purchased it during the relevant period in order to assess the effectiveness of their own sales efforts and to focus their sales efforts on healthcare providers who prescribed high volumes of opioids. By analyzing this data, Keller was able to identify physicians in New York whose prescribing activity would have been flagged by application of Defendants' SOMs metrics. She was also able to determine the number of prescriptions, dosage units, and morphine milligram equivalents ("MMEs") that those physicians' prescriptions represented. Her analysis shows that IQVIA data could have been used by Defendants to identify millions of prescriptions representing billions of dosage units in New York.

Keller also provides case studies of high opioid-prescribing physicians in Suffolk and Nassau counties and in other counties throughout the State. Confirming the reliability of Keller's methodology, all of them triggered one or more of the metrics used. For example:

> Eugene Gosy was both the leading prescriber by volume as well as a leading prescriber per capita in the state. Based in Erie County, Gosy was indicted in 2017 on charges relating to the deaths of six patients whom he prescribed opioids. All major labelers in the state benefitted from Gosy's prescribing until his arraignment despite his being a significant outlier among opioid prescribers in New York. … Gosy wrote millions more opioid prescriptions than other New York pain management specialist. For almost four years, Gosy prescribed at least four million more dosage units per year than the average pain medicine physician statewide.

Keller Rep., NYSCEF No. 5210, at 117 (footnotes and tables omitted). There is no evidence that any Defendant reported Gosy to the authorities. Quite the opposite, Gosy was a target of intensive marketing:

> Mallinckrodt-labeled opioids made up roughly one-third of Gosy's prescriptions and dosage units. Call notes produced by Mallinckrodt indicate that sales representatives logged over 120 calls to Gosy from 2010 to 2014 in promotion of products Exalgo (hydromorphone base) and Xartemis (oxycodone base). Teva, which accounted for another 20% of Gosy's opioid dosage units, also produced call notes that showed the labeler logged over 220 calls to Gosy to market Fentora and Actiq (two fentanyl-based products). Endo, Gosy's third most prescribed labeler, logged at least 400 calls to Gosy from 2008 until shortly before his arrest in 2016. All Endo calls were marketing their oxycodone-based product Opana ER. Sales representatives from Janssen logged

> more than 320 calls to Gosy, with many occurring around the time his prescriptions peaked in 2010. … Consistent with these marketing trends, Gosy's eventual indictment referenced his prescribing patterns of oxycodone, fentanyl, and tapentadol …base codes Xartemis (Mallinckrodt), Fentora and Actiq (Teva), and Nucynta (Janssen), respectively.

Id. at 119-20. When Keller used compliance metrics, Gosy was flagged for 99% of all prescriptions he wrote between 1997 and 2017. *Id.* at 119-21.

Keller also analyzes two other types of data available to the Defendants so-called "chargeback" and "867" data. "Chargeback" data provides Defendants details about distributors' sales to downstream customers, including pharmacies, hospitals, and other dispensers. It was provided to manufacturers in connection with arrangements whereby distributors could charge manufacturers back for unsold drugs or drugs sold at lower than expected prices. Information about opioid shipments is further reflected in "867" data, which provides details about distributors' sales to their downstream customers, broken down by zip code and type of outlet, and it was used by some Defendants in investigations of suspicious prescribers and downstream customers.

Using chargeback and 867 data, Keller was able to identify pharmacies New York whose buying activity would be flagged by the SOMs metrics. She was also able to determine the number of transactions that would be flagged, the number of dosage units that those chargebacks represented, and which Defendants' sales were associated with the flagged transactions.

For analysis of the sales of distributors and retail pharmacies, Keller used the same data that McCann used, the ARCOS data provided by the DEA, as well as data maintained by the New York State Department of Health in the Manufacturers and Distributors of Controlled Substances ("MADOCS") database. Keller's analysis shows that Defendants could have detected the suspicious activity of specific pharmacies – examples of which are profiled in her report – and, had they complied with their legal obligations, they would have stopped billions of dosage units from being dispensed in New York.

Keller provides six case studies of individual pharmacies. For example, BJK Inc., a pharmacy in Nassau,

> purchased millions more dosage units than other pharmacies in New York or across the nation. In 2007, roughly 90% of dosage units that BJK purchased were in excess of the average New York pharmacy's annual purchases that year. Even at its lowest purchasing volume in 2018, BJK still bought almost one million dosage units more than the average statewide or nationwide pharmacy.

Keller Rept., NYSCEF No. 5210, at 84. "According to ARCOS data, at peak in 2007 BJK bought more than 4.2 million dosage units – enough for every man, woman, and child in Long Beach to have roughly 250 estimated 10mg hydrocodone pills that year." *Id.* at 83. As with the physician case studies, the pharmacy case studies confirm the reliability of the metrics that Keller employed. BJK "was flagged for more than 90% of all dosage units it purchased of defendant-labeled opioids, according to the Defendants' own metrics." *Id.* at 86.

The results of Keller's analysis are enlightening:

> My findings demonstrate that there were millions of prescriptions and transactions for billions of dosage units and MMEs in New York that Defendants could have identified as suspicious yet were shipped and often unreported to local or federal authorities. Furthermore, my analysis shows that had Defendants applied their own compliance metrics or other baseline metrics they could have discovered suspicious prescribing and purchasing patterns using standard data-analytic tools on data they had access to or was in their possession.

Id. at 12.

2. *Keller's methodology has a sufficient foundation and will assist the jury in deciding the issues in this case.*

Keller used ten different compliance metrics and applied them to multiple datasets. Each has a sufficient foundation to provide support for her report. In an effort to cast doubt on the legitimacy of the ten metrics, Defendants refer to them as "lawyer-provided algorithms" – as if Plaintiffs' counsel had somehow invented them. *See* Def. Keller Br. at 1. That is nonsense. The first group of algorithms Keller used were the same ones the Defendants themselves used in their own SOMs programs. Thus, those metrics were Defendant-provided. The second group of algorithms she used, called "baseline

metrics," came from Rafalski and McCann, and the decision in *Masters Pharm.* Keller Rept., NYSCEF No. 5210, at 36. Thus, the baseline metrics were provided not by Plaintiffs' lawyers, as Defendants falsely claim, but rather by (i) the United States Court of Appeals for the District of Columbia in the *Masters* case, (ii) a former DEA diversion investigator, and (iii) an economics expert on whom Keller is entitled to rely.

Keller implemented the compliance metrics using both the "persistent" approach described above and used by Dr. McCann, and also a "resetting" approach. Again, there is sufficient foundation for both methods. In contrast to the persistent approach, with the resetting approach, every month the metrics are re-applied as if the physician or pharmacy had never been flagged before for a given drug. This approach, which results in a smaller number of flagged transactions, in effect gives the defendant the benefit of the doubt – as if the defendant had the right, when monitoring for suspicious activity in any given month, to ignore suspicious activity in all previous months. Keller presents the results of both approaches for each defendant and each pharmacy or prescriber example. Keller Rpt., NYSCEF No. 5210, at 36.

Defendants claim that the "persistent" approach used by Keller was "concocted by Plaintiffs' counsel to maximize the number of orders that would be flagged." Def. Keller Br. at 9. As noted above, however, Dr. McCann used this approach, and Rafalski's opinions provide support for it. In any event, the real issue is not who suggested this approach, but whether it is reasonable to use and would assist the trier of fact. Defendants' preference for the "reset" approach depends on the assumption that every month the suspicious order memory banks should be erased, and any suspicions arising from the unusual activities of the past may thereafter be ignored. But that assumption makes no sense. If a buyer of dangerous narcotics has placed an order of such an unusual size that it triggers a suspicious order monitoring system, and if the seller has not performed an of the required due diligence to determine that the order was not in fact likely to be diverted, then any reasonable seller

of dangerous narcotics, mindful of its legal duties to identify, report and stop suspicious orders, would treat all subsequent orders for the same drug by the same suspicious buyer as suspicious. Indeed, Plaintiffs expect that the jury will agree that it would be patently unreasonable for a seller of dangerous narcotics to simply ignore the prior suspicious order history and pretend that it never happened. When it comes to suspicious orders for dangerous narcotics, sellers should have the memory of an elephant, not that of a goldfish.

Defendants also attack the datasets to which Keller applied her metrics. They claim that the DEA's data is inaccurate and incomplete. But they cite only a single example of a report that they allege is missing. This single error – if indeed it was an error – hardly calls into question the reliability of the entire database. Similarly, Defendants argue that because some DEA field offices have discarded the underlying documents on which the data is based that somehow undermines the accuracy of the data. That argument too is meritless. While it may have been DEA policy to retain the underlying paper documents, the fact that old documents were discarded in violation of that policy does not in any way undermine the accuracy of the data that was contemporaneously compiled based on the documents prior to being discarded. Nor are Defendants prejudiced in any way by the loss of the paper records. Since the reports that were discarded were their own reports, they presumably have their own copies, and if they genuinely believe the government's data is materially incomplete or inaccurate, they will be free to try to convince the jury of that at trial. Furthermore, even if Defendants could show that the data was incomplete and inaccurate, that would only go to the weight to be accorded Keller's testimony; it would certainly not preclude her from relying on official data provided by the United States government.

Defendants argue that Keller was required to independently verify the accuracy and completeness of the data contained in the DEA's Suspicious Order Reports Data from 2007-2014. This argument is meritless. An expert is entitled to rely upon data compiled and made available by

agencies of the United States government whose duty it is to compile such data. Reliance on such data certainly does not in any way call into question the reliability of Keller's analysis. Importantly, it should be noted that the United States government, through the DEA, does not compile data on narcotics manufacture and distribution simply because it is curious about that issue, nor does it do so simply because of U.S. government policy. Rather,

> DEA is responsible for fulfilling United Nations' treaty obligations which relate to the international control of certain narcotic drugs and psychotropic substances. ARCOS software provides automated consumption, manufacturing, and inventory data which serve as a basis for establishing the United States' estimates of medical and scientific needs and the establishment and maintenance of inventories. The United States submits these estimates annually to the United Nations' International Narcotics Control Board (INCB), in Vienna, Austria. The INCB uses the United States' estimates to determine worldwide estimates.
>
> DEA also sets annual manufacturing and procurement quotas for Schedules I and II controlled substances under the United States Controlled Substances Act. These quotas cannot be exceeded during the calendar year for which they are given. DEA submits annually to the INCB statistics on the United States' consumption, manufacturing, and year-end inventories of the narcotic drugs and psychotropic substances which are controlled under the 1961 and 1971 Conventions.

ARCOS Registrant Handbook, United States Department of Justice, Drug Enforcement Administration, Diversion Control Division.[17]

Defendants also seek to exclude Keller's testimony arguing that her conclusions are not based on the "real world." Def. Keller Br. at 1. To the extent this is an attempt to suggest that Keller's opinions lack sufficient foundation, the argument should be rejected. To the contrary, Keller's opinions are based on "real world" metrics, applied to "real world" data, relating to "real world" sales, distributions, and prescriptions that, not coincidentally, flagged "real world" pill mills and other sources of diversion. In the "real world," Defendants failed to adequately monitor for suspicious orders. As a result, it is now necessary for an expert to help the jury resolve the hypothetical question

[17] Available at https://www.deadiversion.usdoj.gov/arcos/handbook/section1.htm (accessed on 3/8/20).

of what Defendants would have learned if they had performed their legal duties in the "real world." That does not mean that Keller fails to offer "real world" opinions; rather, is simply means that she has done what experts do all the time: she has answered hypothetical questions based on reasonable, "real world" assumptions, that will help the jury determine the cause of the devastating "real world" consequences of Defendants' "real world" willful or negligent failure to act.

As noted above, Keller was simply applying "math" to very large datasets. She did not invent the methodologies utilized to determine how many suspicious orders existed. Rather, as discussed above, manufacturers, distributors, and pharmacies are free to design whatever SOMs program they feel will best fulfill their duty to identify suspicious orders – that is, "orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." *See* Pltf. SOMs Brief, NYSCEF No. 2849, at 4-5 (*citing* 21 C.F.R. § 1301.74). The MDL court held that Mr. Rafalski's experience as a DEA Diversion Investigator qualified him to identify appropriate methodologies for identifying suspicious orders, and also held that "in determining whether Defendants employed effective measures to identify, investigate, and stop shipments of suspicious orders, it would be helpful to the finder of fact to hear evidence about the number of suspicious orders that each methodology would have flagged." Presnal Aff., Ex. 2 at 11-12. Consequently, Defendants' arguments about the methodologies she applied to the data are without merit.

3. Defendants are not entitled to an order "precluding" Keller from offering any opinion that she has never offered and never said she intends to offer.

Nor is there any need for the Court to enter an order prohibiting Keller from testifying that "flagged" orders are "suspicious" as defined in the CSA, because she has never offered such an opinions.

Keller does not offer any opinion on whether any of Defendants transactions were "suspicious" as that term in used in the CSA and the NYCSA, but her analysis of the data amply supports Plaintiffs' argument that "Defendants' compliance failures caused excess shipments of

millions of suspicious orders." *See* NYSCEF No. 3690 (Plaintiffs' Memorandum of Law in Opposition to Defendants' Motions for Summary Judgment Regarding Proof of Causation) at 16. To the extent Defendants seek to preclude Keller from expressing any opinion regarding whether transactions were "suspicious," their application is meritless, because she has not offered any such opinion and has not said that she plans to offer any such opinion. To the extent Defendants seek to preclude Plaintiffs from arguing to the jury, on the basis of Keller's analysis, that Defendants failed to identify, report and stop suspicious orders, their application is unsupported by any legal authority.

II. The Court should not exclude the opinions of epidemiologist Professor Katherine Keyes.

In their motion addressed specifically to Dr. Katherine Keyes, Defendants move to exclude three of her opinions: (a) that consumption of prescription opioids is causally related to subsequent heroin and fentanyl use, otherwise known as the "Gateway Effect"; (b) that the increased supply of opioids beginning in the 1990s was responsible in part for the increase in the incidence and prevalence of opioid use disorder; and (c) that among chronic pain patients, an estimated 21-29% meet criteria that could be characterized as between mild to severe opioid use disorder, and an estimated 8-12% of patients meet criteria that would be consistent with moderate to severe opioid use disorder. (As discussed above, Defendants separately move to exclude Dr. Keyes's so-called "marketing causation" opinion. That motion is addressed below at Point IV.) Defendants contend that no scientific evidence supports these three opinions and that Dr. Keyes is not qualified to render them because she lacks medical experience. However, Defendants mischaracterize Dr. Keyes' methodology and fail to address the overwhelming majority of the scientific evidence upon which she relies. They also fail to acknowledge that in the MDL, Judge Polster rejected their attempt to preclude Dr. Keyes from offering opinion testimony on the Gateway Effect.

Dr. Keyes, a highly credentialed epidemiologist at Columbia University whose specialty is substance use and substance use disorders, bases her opinions on reliable methodologies that are

generally accepted in her field. In particular, Dr. Keyes relies on an extensive body of scientific literature that: (i) has documented the Gateway Effect; (ii) has established the links between medical use of opioids, non-medical use of opioids, and use of non-prescription opioids; and (iii) provides a solid foundation for her estimates of rates of addiction.

Defendants fundamentally misconstrue Dr. Keyes's proposed expert testimony. Her opinion is that beginning in the 1990s, a rapidly expanding supply of opioids became available in Suffolk, Nassau, and across New York State, which contributed to large numbers of people developing opioid use disorder, through both medical and non-medical use. The massive shipments of opioids that flooded the State caused a rapid increase in overdose deaths due to prescription opioid overdose, and other significant harms such as non-fatal overdoses, increased rates of addiction, and increased rates of neonatal abstinence syndrome. When the rates of supply of prescription opioids began to taper and decline starting in the early 2010s, addicted individuals sought non-prescription opioids, in particular heroin, which was cheaper and more readily available. Heroin – which became a substitute for prescription opioids – caused overdose deaths to increase, and when the heroin supply became tainted with fentanyl, the overdose death rate skyrocketed. Further, the exponential increase in prescription opioid supply and subsequent harms created a large market for the distribution and sale of heroin, which then expanded to new users as well, given that the demand was established. Dr. Keyes explains how these events are causally linked to oversupply of opioids. Defendants attempt to establish a false dichotomy between medical and non-medical use of prescription opioids, which is not supported by the scientific evidence. Dr. Keyes published research regarding the Gateway Effect long before she was retained as an expert in this litigation, which strongly indicates the reliability of her opinions.[18]

[18] *See* Presnal Aff., Ex. 8, Keyes, et al., *Understanding the Rural-Urban Differences in Nonmedical Prescription Opioid Use and Abuse in the United States*, A. J. Public Health 104:e52-e59 at e53 (2014) ("Increased medical use of prescription opioids has resulted in increased access to opioids for nonmedical use, either through the nonmedical use of legitimately acquired prescriptions or through formal or informal distribution networks.").

In the MDL, Defendants unsuccessfully sought to exclude Dr. Keyes's opinions on the Gateway Effect, and their recycled arguments should be rejected by this Court as well.[19] Instead of offering valid critiques of Dr. Keyes's methodology, Defendants engage in a simplistic and misleading series of attacks, mischaracterizing her opinions and misquoting her deposition testimony. Defendants fail to grapple with the fact that through her analysis of hundreds of peer-reviewed scientific articles, Dr. Keyes shows how the risk of opioid use disorder from exposure to prescription opioids follows a dose-response relationship, and how heroin and fentanyl use inexorably flow from prescription opioid use and misuse. Whether Dr. Keyes is a medical doctor or conducted studies expressly for this litigation is utterly irrelevant to the reliability of her opinions. What matters is that she performed a well-reasoned synthesis of scientific literature and data, which easily satisfies the requirements for a proffer of expert testimony under New York law.

Defendants' motion fails as to the Gateway Effect because Dr. Keyes' methodology in forming that opinion is not novel, so the *Frye* test does not apply. Even assuming that *Frye* applies to all three opinions at issue, Defendants' motion should be denied because Dr. Keyes followed generally accepted methodological and epidemiological principles to develop those opinions. Defendants evidently dispute Dr. Keyes's conclusions, but such disagreements do not provide a basis for excluding expert testimony.

A. Dr. Keyes is qualified to offer all three of the opinions at issue

For the most part, Defendants do not – and cannot – seriously challenge Dr. Keyes's qualifications to serve as an expert witness in this case. In the MDL, Judge Polster described her credentials as follows:

[19] Dr. Lembke also addresses the Gateway Effect in depth in her report. While Defendants' challenged those opinions in the MDL, Judge Polster denied their motion to exclude opinions regarding the Gateway Effect offered by both Dr. Lembke and Dr. Keyes. Notably, Defendants have not attempted to exclude Dr. Lembke's Gateway Effect opinions here, which support Dr. Keyes' opinions on the same subject.

> Katherine Keyes is an Associate Professor of Epidemiology at Columbia University, specializing in substance use and substance use disorders epidemiology. She received her Ph.D. in Epidemiology from Columbia University. She has published 225 peer-reviewed articles and book chapters. Her work appears in leading journals such as Pediatrics, JAMA Psychiatry, Lancet Psychiatry, American Journal of Epidemiology, and International Journal of Epidemiology, and is widely cited. Keyes has published two textbooks on epidemiological methods, both with Oxford University Press. She is an elected member of the executive board of the Society for Epidemiological Research and serves as Associate Editor of the journal Drug and Alcohol Dependence. Keyes has received numerous professional awards honoring her research achievements, including early career achievement recognitions from the Research Society on Alcoholism, the American Psychopathological Association, the World Psychiatric Association-Epidemiology and Public Health Section, and the NIH Office of Disease Prevention Early-Stage Investigator award.

Presnal Aff., Ex. 3 at 2.

Dr. Keyes has extensive expertise on opioid-related harm, including conducting large scale survey data and vital statistics analyses, as well as analyzing the role of macro-social factors in producing the opioid epidemic. She has published 21 peer-reviewed journal articles on opioid use and related harms (and many more on drug use disorders generally), detailing trends over time in prescription opioid misuse, birth cohort trends in non-medical opioid use and overdose, risk factors for non-medical prescription opioid use, and consequences of use across developmental periods, including consequences related to overdose. Keyes Report, NYSCEF No. 5212 at 5.

Dr. Keyes has particular expertise on the opioid epidemic landscape of New York, serving as a faculty member and also as a steering committee member of the Substance Abuse Epidemiology Training Program (SAETP) at Columbia University, in which she trains and mentors doctoral and post-doctoral scholars in substance abuse epidemiology. She is also an investigator on the HEALing Communities Study, a National Institutes of Health-funded initiative aiming to reduce opioid overdose by 40 percent in four states, including New York, through implementation and dissemination of evidence-based prevention and intervention efforts, including expanded access to medication for opioid use disorder, distribution of naloxone to reverse overdose, and efforts to reduce high-risk prescribing. For the project, she will develop mathematical simulations of the cycle

of opioid use in New York, and estimate the anticipated reduction in overdose deaths by simulating combinations of intervention initiatives taking into account the system dynamics of various counties within the state. *Id.*

Defendants do argue, however, that Dr. Keyes is not qualified to offer one of the three opinions they challenge, specifically her opinion that

> The expansion of non-medical prescription opioid use would not have occurred without the widespread availability of prescription opioids that were originally dispensed supposedly (but not always actually) for medical uses, often in greater quantities and doses than needed, leaving a surplus of opioids that could be diverted for non-medical uses.

Keyes Report, NYSCEF No. 5212, at 6. Defendants' argument – which is based entirely on the fact that Dr. Keyes is not a medical doctor – is deeply flawed. Defendants mischaracterize Dr. Keyes's opinion, stating that she suggests that the number of opioids dispensed per person was "too high" and that she is opining about the appropriateness of particular opioid prescriptions. Not so. Dr. Keyes presents data showing the dramatic increase in opioid prescriptions filled in New York since the 1990s. Keyes Report, NYSCEF No. 5212, at 13-14. She explains, based on her synthesis of six systematic reviews and meta-analyses that encompass dozens of studies involving hundreds of patients, how the risks of opioid use disorder following medical use of prescription opioids follow a dose-response pattern. In other words, Dr. Keyes analyzes how the risk of opioid use disorder escalates with increasing doses and length of opioid use. *Id.* at 14-19. Dr. Keyes's opinions about the dose-response relationship do not involve a judgment about an appropriate level of supply or the medical appropriateness of opioid prescriptions, but are based on her analysis of reliable data, using generally accepted epidemiological principles.

Defendants fail to recognize that Dr. Keyes's opinion that there is a dose-response relationship between the aggregate supply of opioids and harm is in part based on the fact that opioids are diverted and used by individuals with opioid use disorder and for non-medical use, via two pathways. First,

"*[p]ervasive overprescribing resulted in unused prescribed opioid medications diverted for monetary value, barter, or for no cost among family and individuals in a shared social network*." Second, "*[p]ervasive oversupply led to diversion of opioids through medical providers for the purpose of non-medical use, including individuals obtaining multiple prescriptions across providers, as well as through high-volume prescribers that were not properly regulated*." *Id.* at 20. Both pathways lead to non-medical use of opioids, *id.*, all of which contributes to harm. In other words, for the 12.5 million Americans who use opioids non-medically, *id.*, any access to opioids carries high risks of addiction to prescription opioids, consequent heroin and non-prescription fentanyl use, and serious harms, including overdose death.

Dr. Keyes's opinion that the dramatic increase in opioid supply caused increased harm – from both medical and non-medical use of opioids – is not based on, and does not require, a judgment about the medical necessity of opioid prescriptions or an estimate of the proper supply of opioids. Dr. Keyes discusses numerous studies that have that have found that a substantial proportion of opioids that are dispensed to patients for medical use are not used by the patient, and are diverted. *See, e.g.*, Keyes Report at 20-21, discussing Shei A, Rice JB, Kirson NY, et al. *Sources of Prescription Opioids Among Diagnosed Opioid Abusers*. Curr Med Res Opin. 2015;31(4):779-784.

B. Dr. Keyes employs generally-accepted methods to conclude that prescription opioid use causes heroin and fentanyl use

As a preliminary matter, Dr. Keyes's opinion that both medical and non-medical prescription opioid use causes heroin and non-prescription fentanyl use, *i.e.*, "the Gateway Effect," is not based on novel scientific techniques, which provides a basis for denying Defendants' motion with respect to that opinion. *Nonnon v. City of N.Y.*, 32 A.D.3d 91, 108 (1st Dep't 2006) ("as neither the epidemiological reports nor the toxicological submissions concern 'novel science,' *Frye's* concerns are not implicated and no pretrial hearing was required"). Rather, the methodology used by Dr. Keyes to form her opinions on the Gateway Effect – review and synthesis of scientific literature – is well-established. *See Kurz v. St. Francis Hosp., Roslyn, New York*, 47 Misc. 3d 184, 193 (N.Y. Sup. Ct. 2014) ("It is sufficient

if a synthesis of various studies or cases reasonably permits the conclusion reached by the plaintiff's expert."). Similarly, the epidemiological methods used in the underlying studies are not novel, but rather are well-accepted in the scientific community. Indeed, in this instance, both the methodology *and* the conclusion are well-accepted.

The Gateway Effect has been repeatedly validated in studies published in peer-reviewed scientific journals over a period of many years. More than a decade ago, a study of heroin users in Wilmington, Delaware, found that "most reported that prescription opioids were indeed their gateway to heroin use."[20] Dr. Keyes reviewed 16 studies on the Gateway Effect, finding that they show that "individuals who use prescription opioids non-medically have higher rates of injecting and snorting heroin than individuals who do not use prescription opioids, even after controlling for health and mental health, as well as demographics." Keyes Report, NYSCEF No. 5212, at 37. Dr. Keyes concluded that, although it is not possible for ethical reasons to conduct randomized controlled trials to study the risk of heroin use following prescription opioid use, the observational studies she discussed were "sufficiently diverse in population and design while consistent in their results in order to draw the conclusion that prescription opioid use is causally related to heroin use." *Id.*

Dr. Keyes appropriately relies upon epidemiological studies that have replicated the finding that the vast majority of heroin users initiated opioid use with prescription opioids. For example, Cicero[21] found that up to 75% of heroin users initiated opioid use with prescription opioids,

[20] J. Inciardi, *et al.*, *Prescription Opioid Abuse and Diversion in an Urban Community: The Results of an Ultra-Rapid Assessment*. Pain Medicine 10:537-548, 544 (2009), cited in the Keyes Report, NYSCEF No. 5212, at 20.

[21] *See* Cicero, *et al.*, *The Changing Face of Heroin Use in the United States: A Retrospective Analysis of the Past 50 Years*, JAMA Psychiatry 2014; 71 (7): 821-826, at p.823 ("75% of those who began their opioid abuse in the 2000s reported that their first regular opioid was a prescription drug."), cited in Keyes Rep., NYSCEF 5212, at 37.

Lankenau[22] found that the figure was up to 87%, and Muhuri[23] found that the figure was up to 80%. Dr. Keyes also relies on four rich ethnographic studies conducted in New York City, which document the transition between prescription opioids and heroin use. Keyes Report, NYSCEF 5212, at 37-38.[24]

Dr. Keyes published on the Gateway Effect before becoming involved in opioid litigation. Dr. Keyes' pre-litigation, peer-reviewed publications focused on questions that are directly relevant to, and supportive of, the validity of the Gateway Effect. In a study published in 2015, Dr. Keyes wrote, *"Legitimate opioid use by 12th grade significantly predicts future opioid misuse after high school."*[25] Dr. Keyes also reported in a 2014 article: "Increased medical use of prescription opioids has resulted in increased access to opioids for nonmedical use, either through the nonmedical use of legitimately acquired prescriptions or through formal or informal distribution networks.… [t]he nonmedical prescription opioid use epidemic may portend future increases in illicit drug use as well, considering that *nonmedical*

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[22] *See* Lankenau, *et al.*, *Initiation into Prescription Opioid Misuses Amongst Young Injection Drug Users*, Int. J. Drug Policy 2012; 23(1):37-44, at p.41. (86.6% percent of people who used injected heroin in New York and Los Angeles in 2008 and 2009 had used prescription opioids nonmedically before using heroin), cited in Keyes Rep. NYSCEF 5212, at 37.

[23] *See* Muhuri, *et al.*, *Associations of Nonmedical Pain Reliever Use and Initiation of Heroin Use in the United States*, CBHSQ Data Rev. 2013; (August):1-16, at p. 1. (79.5% of persons who recently began using heroin had used prescription opioids nonmedically before initiating heroin use), cited in Keyes Rep., NYSCEF 5212, at 38

[24] Defendants criticize Dr. Keyes for not providing what they call "a valid point of comparison," which could address their alternative hypotheses regarding heroin use. But Defendants fail to explain why an expert is required to rule out alternative hypotheses, and an expert is not required to account for alternative explanations and confounding factors. *See Nonnon v. City of N.Y.*, 32 A.D.3d 91, 108 (1st Dep't 2006) (supposed failure to account for factor is subject for cross examination at trial and goes to the weight of the evidence).

[25] *See* R. Miech, *et al.*, *Prescription Opioids in Adolescence and Future Opioid Misuse,* Pediatrics, Volume 136:e1169-1177 at e1173 (2015) (emphasis added) cite in Keyes Rep., NYSCEF No. 5212, at 23. The editors added the following comment to Dr. Keyes's article, further supporting the validity of the Gateway Effect: "Legitimate opioid is a risk factor for subsequent misuse of opioids among adults. This study provides the first population-based estimate of the risk of future opioid misuse associated with legitimate opioid use among adolescents." *Id. at* e1169. In the context of the opioid epidemic, Plaintiffs use and understand the term "legitimate" to mean only that the user took a drug prescribed by a doctor, in accordance with instructions. The term should not be interpreted to confer "legitimacy" on the enterprise of vastly overprescribing opioids based on false and misleading representations regarding claimed benefits and purported absence of risk when taken pursuant to a doctor's prescription.

prescription opioid users are more likely than are nonusers to transition to heroin and other illicit drugs."[26] These two articles supporting the Gateway Effect were researched, peer-reviewed and published by Dr. Keyes three years prior to beginning work in the opioid litigation. Dr. Keyes' pre-litigation publications of her findings, which match her opinions in this case, provide further assurance of the reliability of her opinions. Even an expert retained by Defendants in this case, Dr. Peggy Compton, publicly endorsed the Gateway Effect five years ago:

> A particularly worrisome trend in the United States is the recent rise in heroin use. The National Survey on Drug Use and Health (NSDUH) estimated that the number of Americans having used heroin in the past 30 days rose from 373,000 to 620,000 between 2007 and 2011. Contributing to this increase are [prescription opioid] abusers who transition to heroin use, with the prescribed opioid serving as a "gateway drug" to the illicit one.[27]

Defendants' expert has stated that evidence of the Gateway Effect was reported as far back as 2003.[28] The abundant evidence presented above shows that the Gateway Effect is not a novel theory, or based on novel techniques. Defendants' argument that no controlled clinical trials have shown the Gateway Effect is specious, because it would be unethical, and therefore impermissible, to expose one group to addictive drugs and compare them to an unexposed group.

Defendants contend that because none of the studies Dr. Keyes cites studied medical users of opioids, she lacks a basis to conclude that medical use of prescription opioids caused heroin use. Defendants' distinction between medical and non-medical use is misplaced, as studies show that "the majority of [non-medical use by addicts] involved a history of medical use."[29] Medical users of

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[26] *See* Katherine Keyes, *et al.*, *Understanding the Rural–Urban Differences in Nonmedical Prescription Opioid Use and Abuse in the United States.* A. J. Public Health, 104:e52–e59, at e53 (2014) (emphasis added).

[27] *See* Kanouse AB, Compton P, *The Epidemic of Prescription Opioid Abuse, the Subsequent Rising Prevalence of Heroin use, and the Federal Response.* J Pain Palliat Care Pharmacother. 2015 Jun;29(2):102-14.

[28] *Id.*

[29] *See* S. McCabe, *et al., Trends in Medical and Nonmedical Use of Prescription Opioids Among U.S. Adolescents: 1976-2015.* Pediatrics 139, Number 4 (2017) at 9, cited in Keyes Rep., NYSCEF No. 5212, at 18.

prescription opioids become nonmedical users of those same addictive drugs, who then become heroin users. In other words: a patient who starts with a valid opioid prescription and abides by its limitations (a "medical user") may then become addicted and breach those limitations (becoming a "non-medical user") and may then turn to non-prescription opioids. In this way, the original, legitimate opioid prescription can serve as a gateway to heroin.

Defendants also argue that the epidemiological evidence does not show that even non-medical use of prescription opioids caused heroin and non-prescription fentanyl use. However, Dr. Keyes applied a generally accepted methodology by relying on the scientific studies cited above, which show, at a minimum, that nonmedical use of opioids does lead to heroin use. The data set forth in the studies have sufficient indicia of reliability to show causation, including strength of association, dose-response relationship, and temporal relationship – all attributes that support a causal relationship between prescription opioid use and non-prescription opioid use. Keyes Report, NYSCEF 5212, at 37-39.

In the MDL, Judge Polster considered Defendants' argument that none of the above-referenced studies linking prescription opioid use and heroin use specifically address medical use of opioids – which they repeat here – and rejected it, ruling:

> In the scope of the opioid epidemic, there is no meaningful distinction between (i) patients who started using prescription opioids as prescribed, but then began to overconsume because of dependence or addiction, and (ii) non-medical users who somehow overconsumed for other reasons. Likewise, some evidence suggests those who used prescription opioids without a prescription had the opportunity to do so because of the overabundance of these drugs in the medicine chests of their relatives or friends. Defendants' first contention, that the Experts' testimony must be excluded because none of the literature the Experts cite studied "medical users" of opioids, is, therefore, not well-taken. Defendants may explain to the jury why the distinction between these two populations in the literature is important; the distinction goes to the weight of the Experts' testimony, not its admissibility.

Presnal Aff., Ex. 3 at 7. The validity of Judge Polster's decision is reinforced by additional studies cited by Dr. Keyes that document that opioids prescribed for medical use are diverted to non-medical use. For example, a recent study of medical records showed that, among individuals with an opioid

use/dependence diagnosis, 79.9% of individuals had at least one claim for a prescription opioid prior to diagnosis.[30]

Dr. Keyes also discusses a 2014 study by Edlund[31] that used claims data from a healthcare database for patients who had been prescribed opioids by their doctors, for various acute and chronic conditions -- precisely the population who would not be at risk of addiction if Defendants' claims were true[32]. Significantly, Edlund applied an "incidence" methodology, which assured that patients had neither recent opioid prescriptions nor opioid use disorder ("OUD") diagnoses prior to the start of the study; thus, the observed effects were most certainly due to the new onset of OUD, rather than any pre-existing condition. Edlund found that there was a dose-response relationship between dose and length of opioid use, and a new diagnosis of opioid use disorder. Among those who had high-dose opioids for a greater number of days, the incidence of new opioid use disorder was 6.1, and the risk of developing opioid use disorders was 122.5 times higher than those with no opioid use, after adjustment for age, sex, indicators of pain and mental disorders, and that even at very low levels of use, the risk of opioid use disorder diagnoses was significantly higher than for those with no opioid use. As shown by Edlund, patients who receive properly prescribed opioids become an ongoing source of non-medical users who provide a feeder population for illicit drug use.

Defendants criticize Dr. Keyes for not citing a 2019 study by McCabe, which they argue (without any support) is the "best available evidence" and shows that medical use of prescription opioids during adolescence does not increase the risk of substance use disorder later in life. However, the McCabe 2019 study reinforces the intertwined nature of medical and non-medical use of opioids.

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[30] Shei A, Rice JB, Kirson NY, et al. *Sources of Prescription Opioids Among Diagnosed Opioid Abusers*. Curr Med Res Opin. 2015;31(4):779-784 cited in Keyes Rep., NYSCEF No. 5212, at 20.

[31] Edlund, *et al.*, *The Role of Opioid Prescription in Incident Opioid Abuse and Dependence Among Individuals with Chronic Noncancer Pain*, Clin. J. Pain 30(7): 557-564 (2014), cited in Keyes Rep., NYSCEF No. 5212, at 18.

[32] Keyes Rep. NYSCEF No. 5212, at 18.

Defendants fail to mention this key finding: "Approximately one-half of adolescents who reported the medical use of prescription opioids after initiating NMUPO (49.5%) or only NMUPO (53.3%) during adolescence had SUD symptoms at age 35."[33]

Dr. Keyes does discuss the McCabe 2017 study,[34] which is based on large-scale surveys of adolescents, and showed that adolescent non-medical use of opioids is frequently preceded by medical use in the adolescent population. McCabe's conclusions in the 2017 study provide strong support for the Gateway Effect: "The findings provide compelling evidence that medical use of prescription opioids and [non-medical use of prescription opioids, or "NUPO"] are highly correlated, especially among adolescents. . . . We found that the majority of NUPO involved a history of medical use, and this finding should provide some concern to health professionals who prescribe opioid medications to adolescents, given the serious health consequences associated with NUPO."

Defendants' argument that the Gateway Effect should not extend to the link between heroin and fentanyl is also misplaced. Much of the research linking prescription opioid exposure to illicit opiates was based on data that preceded the spike in illicit fentanyl use, and thus the studies generally refer to heroin as the target illicit drug following prescription opioids. Dr. Keyes properly concluded, however, that the same pathway would apply to illicit fentanyl. Part of the reason for this

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[33] *See* S. McCabe, *et al.*, *A Prospective Study of Nonmedical Use of Prescription Opioids During Adolescence and Subsequent Substance Use Disorder Symptoms in Early Midlife*, Drug Alcohol Dependency (2019), at 381. During her deposition, Dr. Keyes explained a significant limitation of the McCabe 2019 study with respect to its conclusion regarding the link between medical use of opioids and nonmedical use:

> So what this study examines, by medical use only, as described in the measure section, is, asking respondents whether they had ever taken prescription Opioids because a doctor told them to use the medication. So I think the appropriate characterization of that group is self-reported lifetime medical use at age 18. And for those individuals who self-reported medical use at age 18, who did not additionally self-report nonmedical use at age 18, the observed risk ratio is reported in these four columns.

Presnal Aff., Ex. 9 (Keyes Dep. Tr. at 360:12-24).

[34] *See* S. McCabe, *et al.*, *Trends in Medical and Nonmedical Use of Prescription Opioids Among U.S. Adolescents: 1976-2015*. Pediatrics 139, Number 4 (2017), at 1, cited in Keyes Rep., NYSCEF No. 5212, at 18.

is that heroin use necessarily exposes patients to fentanyl as well, due to the widespread fentanyl contamination of the heroin supply. As noted by a CDC document upon which Dr. Keyes relies, fentanyl "is often mixed with heroin and/or cocaine as a combination product – with or without the user's knowledge – to increase its euphoric effects."[35] Therefore, the same sources cited by Dr. Keyes as evidence of the Gateway Effect of prescription opioids apply equally to both heroin and fentanyl, and she properly relied on these sources for their conclusions with respect to both heroin and fentanyl. Dr. Keyes supports her opinion on the Gateway Effect by citing valid observational evidence showing that restricting prescription opioid supply among those who are dependent on opioids leads to an increase in heroin use and with risky patterns of use – such as use of fentanyl-laced heroin – that cause opioid-associated death. Keyes Report at 39.

In the MDL, taking into account the 2019 McCabe study, Judge Polster ruled that Dr. Keyes may testify regarding the casual links between prescription opioid use (both medical and non-medical, prescription opioid use and heroin, and subsequent fentanyl use, stating:

> But there is still reliable evidence from which one may reasonably infer that some heroin addiction results from opioid use. The strongest evidence is based on studies centered on non-medical users, but as the NASEM report stated, "[a] preponderance of evidence suggests that the major increase in prescription opioid use beginning in the late 1990s has served as a gateway to increased heroin use." NASEM Report at 215. The NASEM report further noted "the interrelated nature of the prescription and illicit opioid epidemics means that one cannot be addressed separately from the other." *Id.* at 248. The Muhuri, Lankenau, and Cicero studies provide a sturdy basis for the Experts' opinions; the Experts' reliance on *observational studies* simply reflects that these studies are the best evidence the discipline can point to where, as in the case of addiction to illicit and deadly substances, controlled clinical studies are not feasible. And Defendants' reference to the low proportion of prescription opioid users who go on to use heroin is a red herring, for the Experts do not opine that most people who use prescription opioids became addicted to heroin; rather, they opine that most people who are addicted to heroin first used prescription opioids.

MDL Gateway Ruling, Ex. 3 at 11.

[35]Ctrs. for Disease Control and Prevention, *Fentanyl*, available at https://www.cdc.gov/drugoverdose/opioids/fentanyl.html.

C. Dr. Keyes used generally-accepted methods to estimate the prevalence of opioid use disorder.

Defendants contend that Dr. Keyes's estimate of the prevalence of opioid use disorder among patients with chronic pain lacks support in generally accepted methods. Specifically, Defendants seek to preclude Dr. Keyes from testifying regarding the calculations she made in the following sentence on page 16 of her report:

> The summary of the evidence presented by Vowles et al. (2015) is that among chronic pain patients, an estimated 21-29% of patients meet criteria that would be characterized as between mild to severe opioid use disorder, and an estimated 8-12% of patients meet criteria that would be consistent with moderate to severe opioid use disorders.

Keyes Report NYSCEF No. 5212, at 16. Defendants also object to Figure 1, which visually depicts these numbers.

Defendants' argument is misplaced because Dr. Keyes used generally-accepted epidemiological methods to calculate her estimates. The source that Dr. Keyes used to begin her analysis, the Vowles systematic review and data synthesis, is itself very reliable, as one of Defendants' experts has testified. Moreover, Dr. Keyes reviewed the dozens of studies analyzed by Vowles to determine the highest quality studies. Keyes Report, NYSCEF 5212, at 15-16. Such epidemiological studies "are by no means a novel methodology for demonstrating a causal relationship between a chemical compound and a series of symptoms or a disease." *Jackson v. Nutmeg Techs., Inc.*, 43 A.D.3d 599, 601 (3d Dep't 2007). Reliable medical and scientific literature may establish an objective basis for an expert's opinions even where such studies are not "exactly parallel to those under consideration in the litigation." *Zito v. Zabarsky,* 28 A.D.3d 42, 44 (2d Dep't 2006); *Kurz v. St. Francis Hosp., Roslyn, New York*, 47 Misc. 3d 184, 193 (N.Y. Sup. Ct. 2014) (rejecting *Frye* challenge in medical malpractice case). "It is sufficient if a synthesis of various studies or cases reasonably permits the conclusion reached by the plaintiff's expert." *Id.* This is especially true here, as Dr. Keyes analyzed and integrated data regarding the incidence of opioid use disorder-related symptoms among patients prescribed opioids

for chronic pain, as reflected in peer-reviewed studies. Dr. Keyes mapped these symptoms to current diagnostic criteria in order to determine estimates rates opioid use disorder.

Dr. Keyes explained that Vowles, in analyzing 38 studies, categorized data regarding symptoms reflecting problematic opioid use into three categories: misuse, abuse, and addiction. Keyes Report, NYSCEF 5212, at 15. Then Dr. Keyes mapped the two most salient categories – misuse and addiction – to the mental health and substance use disorder diagnostic criteria used by clinicians and researchers, the Diagnostic and Statistical Manual of the American Psychiatric Association, Fifth Edition (the "DSM-V"). Dr. Keyes explained that it was proper for her to map Vowles's category of opioid misuse to the DSM-V diagnosis of opioid use disorder because "the measurement of opioid misuse includes criteria of opioid use disorder (use more than intended or prescribed; difficulties with responsibilities as to work, school, appointments, etc.)" and "the category of 'misuse' includes the full spectrum of DSM-V categories, from mild (defined as 2-4 criteria met) to severe OUD (8+ criteria met)." *Id.* Dr. Keyes also explained that it was proper for her to map Vowles's category of addiction to the DSM-V diagnosis of opioid use disorder because "the disorders assessed as 'addiction' … generally correspond to opioid use disorders that range from moderate (5-7 symptoms) to severe (8+ symptoms)." *Id.*

Defendants criticize Dr. Keyes for using overbroad definitions of opioid misuse and addiction, but she used Vowles's definition of misuse ("Opioid use contrary to the directed or prescribed pattern of use, regardless of the presence or absence of harm or adverse effects," Vowles at 570), and Vowles's definition of addiction ("Pattern of continued use with experience of, or demonstrated potential for, harm (eg, 'impaired control over drug use, compulsive use, continued use despite harm, and craving')," *id.*). Dr. Keyes cites the Meltzer study[36], which was included in Vowles's systematic review, which

[36] Meltzer EC, Rybin D, Saitz R, et al. Identifying prescription opioid use disorder in primary care: diagnostic characteristics of the Current Opioid Misuse Measure (COMM). *Pain.* 2011;152(2):397-402 cited in Keyes Rep., NYSCEF No. 5212, at 15. In the Meltzer study, the authors concluded that a self-report assessment of past-

demonstrates that mapping symptoms to diagnostic categories is standard epidemiological practice.[37] Where – as here – an expert's opinion is "based on more than a theoretical speculation, or scientific hunch, the lack of textual authority directly on point pertains to the weight to be given to the expert's testimony, but does not preclude its admissibility." *Kurz v. St. Francis Hosp.*, 47 Misc.3d 184, 193 (Sup. Ct. Nassau Cty. 2014).

Defendants acknowledge that rates of opioid addiction are high, citing to an American Psychiatric Association web page that states that rates of opioid addiction are up to 19%.[38] The web page also states that at least 45 percent of people who use heroin started with an addiction to prescription opioids and that "[p]eople misusing opioids may try to switch from prescription pain killers to heroin when it is more easily available," confirming Dr. Keyes's opinion about the Gateway Effect.

It is apparent that Defendants disagree with the numbers included in Dr. Keyes's estimate of the incidence of opioid use disorder – in other words, her conclusions – rather than with her methodology. The *Frye* test is not concerned with the reliability of an expert's conclusions, but rather with whether an expert's deductions are based on principles that are sufficiently established to have gained general acceptance as reliable. *Nonnon v. City of N.Y.*, 32 A.D.3d 91, 103 (1st Dep't 2006). Dr. Keyes's calculations, which rely on peer-reviewed studies, are based on generally acceptable principles.

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month aberrant medication-related behaviors was a promising tool for identifying those with PDD, which was a diagnosis under a precursor to the DSM-V.

[37] Defendants appear to criticize Dr. Keyes for basing her estimates on the DSM-V, whereas some of the studies she cites used a prior edition of the DSM. This is immaterial, because Dr. Keyes does not rely on diagnostic criteria used by prior editions of the DSM, but rather relies on the symptoms analyzed in the studies cited by Vowles, mapping them to the DSM-V.

[38] *See* American Psychiatric Association, "Opioid Use Disorder," available at https://www.psychiatry.org/patients-families/addiction/opioid-use-disorder/opioid-use-disorder.

III. The Court should not exclude the testimony of physician and addiction specialist Dr. Lembke.

Defendants seek to exclude the opinions of Dr. Anna Lembke, a physician and addiction specialist. Dr. Lembke serves as the Chief of the Addiction Medicine Dual Diagnosis Clinic, the Medical Director of Addiction Medicine, and the Program Director of the Addiction Medicine Fellowship, in the Department of Psychiatry and Behavioral Sciences at Stanford University School of Medicine.[39] She has been licensed to practice medicine since 1995 and is board certified in psychiatry, neurology and addiction medicine. She regularly treats patients with addiction to opioids and other substances. For the last 15 years, her clinical practice has included a significant proportion of patients taking prescription opioids for pain relief, for whom such drugs have resulted in misuse, dependence, and addiction.

Based on her 20 years as a practicing physician, and her research on the opioid epidemic, Dr. Lembke has knowledge and experience concerning the "path of opioid pills from the manufacturers to distributors to pharmacies to patients."[40] In her experience as a physician, Dr. Lembke has frequent interactions with pharmacies and understands that although "pharmacies cannot dispense opioids without a prescription, . . . they also have a responsibility to patient consumers to ensure that [they have] an appropriate prescription and that it's a true prescription, it's not a prescription that will harm the patient."[41] In sum, "pharmacists are not merely in a passive role of turning over opioids or other

[39] Lembke Report, NYSCEF No. 5213, at 1-5.

[40] Presnal Aff., Ex. 10 (Lembke Tr. 24:9-19).

[41] Presnal Aff., Ex. 10 (Lembke Tr. 30:2-22; 49:18-50:20; 137:1-20) (explaining, "pharmacists are an important link in the opioid supply chain" related to the "rising tide of the number of pills in the community, increasing access both through legitimate and illicit means, putting the population at risk," as set forth in the "Tsunami Effect" section of her report, see Lembke Report at 84-88); 139:18-141:1 (describing ways that pharmacists contributed to the oversupply and resulting harms by failing to scrutinize prescriptions for patients of pill mill doctors, and for high-dose / long-duration prescriptions, or in combination with benzodiazepines, which increased patients" risk of accidental overdose death).

medications when they get a prescription. They have also a health-safety relationship with their patients."[42]

In 2016, Dr. Lembke published her influential book, *Drug Dealer, MD: How Doctors Were Duped, Patients Got Hooked, and Why It's So Hard to Stop.*[43] In her book, Dr. Lembke describes the "misconceptions" promoted by Defendants, and, most importantly, the role of those misconceptions in the rise of the opioid epidemic. Among the misconceptions Dr. Lembke identifies are the alleged low risk of addiction and the supposed benefits of opioid use – the same falsities she discusses at length in her expert report in this case. Dr. Lembke's book was based on her independent research prior to any connection to opioid litigation, and her expertise was honed by years of research into relevant scientific and governmental reporting, including the authoritative report of the National Academies of Sciences, Engineering & Medicine (NASEM).[44] Dr. Lembke also relied on this research in developing her report for this case, supplemented by her review of recent academic publications and documents produced in the case.

In questioning Dr. Lembke's qualifications to serve as an expert witness, Defendants do not suggest that her credentials or her years of on-the-ground clinical experience and academic expertise are insufficient to qualify her for the opinions being offered in her report. Rather, Defendants misconstrue Dr. Lembke's testimony, contending that she is not qualified to offer *particular* opinions – opinions which, in fact, she has *not* offered. Plaintiffs do not assert that Dr. Lembke offers any opinions other than those contained in her report, nor do Plaintiffs anticipate asking Dr. Lembke to offer legal opinions in this case. As a researcher and expert on the opioid epidemic, Dr. Lembke has

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[42] Presnal Aff., Ex. 10 (Lembke Tr. 30:2-22).

[43] *See, e.g.,* "A Doctor's Guide to What to Read About the Opioid Epidemic," https://www.nytimes.com/2018/12/17/books/review/opioid-abuse-drug-dealer-anna-lembke.html.

[44] Nat'l. Acads. of Scis., Eng'g & Med., *Pain Management and the Opioid Epidemic: Balancing Societal and Individual Benefits and Risks of Prescription Opioid Use* at v-vi (The Nat'l Acads. Press 2017).

formed her own personal opinions on issues related to the distribution and marketing of opioids. But, in relation to this case, Plaintiffs seek to proffer her expert testimony only with regard to the opinions she outlined in her report.

A. Dr. Lembke properly disclosed her opinions in her report.

Dr. Lembke is well-qualified to offer the reliable opinions offered in this matter. Her nine opinions include:

> 1. Addiction is a chronic, relapsing and remitting disease with a behavioral component, characterized by neuroadaptive brain changes resulting from exposure to addictive drugs. . . . One of the biggest risk factors for addiction is simple access to addictive drugs. When supply of an addictive drug is increased, more people become addicted to and suffer the harms of that drug. Prescription opioids are as addictive as heroin, and the Defendants' conduct in promoting increased supply and widespread access to prescription opioids has resulted in an epidemic of opioid addiction and overdose death.
>
> 2. Opioid prescribing began to increase in the 1980's, and became prolific in the 1990's and the early part of the 21st century, representing a radical paradigm shift in the treatment of pain, and creating more access to prescription opioids across the United States.
>
> 3. The Pharmaceutical Opioid Industry contributed to the paradigm shift in opioid prescribing through promotional materials and its use and manipulation of key opinion leaders, continuing medical education courses, professional medical societies, the Federation of State Medical Boards, and the Joint Commission to convey misleading messages about the safety and efficacy of prescription opioids.
>
> 4. No reliable scientific evidence shows that long-term opioid therapy is effective for chronic non-cancer pain.
>
> 5. Increased supply contributed to more individuals becoming addicted to opioids, including those who turned from prescription opioids to illicit sources of opioids such as heroin (The Gateway Effect).
>
> 6. Increased supply contributed to more individuals, including newborns, becoming dependent on opioids, increasing their risk for opioid-related morbidity and mortality (The Dependence Effect).
>
> 7. Increased supply contributed to more diversion of prescription opioids, causing a dramatic increase in the widespread availability of opioids, including to individuals for whom opioids had not been prescribed (The Tsunami Effect).

> 8. The increased supply of prescription opioids through licit and illicit sources resulted in a prescription opioid epidemic in the United States. "Epidemic," defined as an outbreak of disease that spreads quickly and affects many individuals at the same time, is the appropriate term to describe the increase in opioid related morbidity and mortality beginning in the 1990's and continuing to the present day.
>
> 9. Today's opioid crisis would not have occurred without the paradigm shift that resulted in overprescribing and excessive supply of opioids, which together contributed to the scourge of addiction and death.

Lembke Report, NYSCEF No. 5213, at 5-6.

Absent from these opinions are what Defendants' seek to exclude: "(1) pharmaceutical distributors' responsibility to identify and report suspicious orders and to prevent diversion, (2) alleged collusion among supply-chain participants, and (3) the obligations of the Pharmacy Defendants to their patient-customers." *See* Defs.' Lembke Br. at 1-2. This is because Dr. Lembke is not offering these "opinions" – these were elicited by Defendants during her deposition. Defendants attempted to create a "straw man" by falsely suggesting that Dr. Lembke is offering these opinions when they are nothing more than a good-faith response to questions asked at her deposition.[45] To be clear, Dr. Lembke is not offering opinions on the Distributor or Pharmacy Defendants' duties under the federal or New York Controlled Substance Acts. Nor is she opining on Defendants' collusion, which is a legal conclusion, outside the purview of expert testimony.[46] *See, e.g.*, *Episcopal Diocese of Long Island v. St. Matthias Nondenominational Ministries, Inc.*, 69 N.Y.S.3d 664, 666 (2d Dep't 2018) ("Expert opinion as to a legal conclusion is impermissible.").

Instead, Dr. Lembke's core opinion is:

> As the opioid supply increased, and opioids became more accessible to all Americans, opioid use has increased, and with it the rates of opioid addiction. The nearly quadrupling of opioid prescribing between 1999 and 2012, combined with widespread

[45] *See* Presnal Aff., Ex. 10, Lembke Tr. 25:18-19:9 (confirming her report contains a comprehensive explanation of her opinions and that she does not intend to offer other opinions not in her report).

[46] Defendants take issue with Dr. Lembke's testimony about the pharmaceutical industry is a "billion-dollar industry" and "the money was so appealing." Defs.' Br. 8. Plaintiffs do not intend to elicit testimony from Dr. Lembke on the motive or intent, or the profit margins, of Defendants.

> distribution of those opioids to every corner of America, does not merely correlate with rising rates of opioid addiction and related deaths. It is causative.[47]

This opinion is supported by scientific literature and research.[48] In her report, Dr. Lembke cites to several sources on which she relied.[49] For example, the Association of Schools & Programs of Public Health (ASPPH) Report, "Bringing Science to Bear on Opioids" (Nov. 1, 2019), found "[t]he *tremendous expansion of the supply* of powerful (high-potency as well as long-acting) prescription opioids led to scaled increases in prescription opioid dependence, and the transition of many to illicit opioids, including fentanyl and its analogs, which have subsequently driven exponential increases in overdose." The report also stated that addiction, or Opioid Use Disorder, "is caused by repeated exposure to opioids."

The National Academies of Science, Engineering and Medicine (NASEM) 2017 report, "Pain Management and the Opioid Epidemic: Balancing Societal and Individual Benefits and Risks of Prescription Opioid Use," found "that diversion is a key contributor to increased exposure to prescription opioids."[50] "The DEA (2016b, p. 34) reports that in recent years, distributors in the United States disbursed 12–15 billion dosage units of opioid narcotics to retail-level purchasers, suggesting that total diversion is on the order of 2.5–4.0 billion dosage units."[51] "A *Washington Post* analysis of federal ARCOS data shows that from 2006-2012, approximately 76 billion oxycodone and hydrocodone pills were delivered in the United States."[52] Dr. Lembke summarized "[a]t the same rate

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[47] Lembke Report, NYSCEF No. 5213, at 11.

[48] *See* Presnal Aff., Ex. 10 (Lembke Tr. 26:14-29:14) (discussing support for the opinion that diversion of prescription opioids caused a dramatic increase in the widespread availability of opioids).

[49] Lembke Report, NYSCEF No. 5213, at 11-12.

[50] Lembke Report, NYSCEF No. 5213, at 12.

[51] Lembke Report, NYSCEF No. 5213, at 12 (quoting NASEM at 223).

[52] Lembke Report, NYSCEF No. 5213, at 12 (quoting Scott Higham *et. al., 76 Billion Opioid Pills: Newly Released Federal Data Unmasks the Epidemic*, Washington Post, July 16, 2019).

of diversion reported by NASEM for the period it reviewed, that would represent diversion on the order of 12-19 billion pills during the six year period from 2006-2012."[53]

Dr. Lembke also relies on analysis of the ARCOS data on opioid prescribing that shows "a 9% increase in opioid-related hospitalizations for each one morphine milligram equivalent increase in opioid sales at the county level."[54] She concludes that "[t]hese data demonstrate a clear and convincing geographic-specific link between opioid dispensing and opioid related harm."[55]

It is well-established that this kind of review and assessment of scientific literature is a reliable methodology. *See, e.g.,*. *LaRose v. Corrao*, 963 N.Y.S.2d 712 (2d Dep't 2013) (holding that medical literature presented to the court established that the theory had an objective basis and was founded upon far more than theoretical speculation or a scientific hunch in medical malpractice case); *People v. Scoon*, 756 N.Y.S.2d 100, 101-02 (2d Dep't 2003) (holding that *Frye* hearing was unnecessary where expert's testimony was supported by medical literature and previous judicial opinions in criminal case concerning alleged shaking of deceased child); *Kurz v. St. Francis Hosp., Roslyn, New York*, 4 N.Y.S.3d 475, 481 (N.Y. Sup. Ct. 2014) ("It is sufficient if a synthesis of various studies or cases reasonably permits the conclusion reached by plaintiff's expert.").[56]

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[53] Lembke Report, NYSCEF No. 5213 at 12.

[54] *Id.* at 85 (citing Ghertner R. U.S. County Prevalence of Retail Prescription Opioid Sales and Opioid-Related Hospitalizations from 2011 to 2014. *Drug and Alcohol Dependence* 194 (2019) 330–335, at p.330); Presnal Aff., Ex. 10, Lembke Tr. 27:11-30:1.

[55] Lembke Report, NYSCEF No. 5213, at 85.

[56] *See also Smith v. Pfizer Inc.*, 714 F. Supp. 2d 845, 856 (M.D. Tenn. 2010) (finding expert's reliance on and frequent cites to scholarly articles and studies to be a reliable methodology); *Ferguson v. Lear Siegler Servs., Inc.*, No. 1:09CV635-MHT, 2012 WL 1058983, at *5 (M.D. Ala. Mar. 28, 2012) (finding the evidence the expert relied on in reaching his conclusion (a combination of peer-reviewed articles and experimentation conducted by others) is reliable and he applied it in a manner consistent with scientific principles); *Tressler v. BNSF Ry. Co.*, No. CV-10-188-RMP, 2012 WL 315402, at *6 (E.D. Wash. Feb. 1, 2012) (finding medical and scientific literature review and evaluation of available epidemiological data is reliable methodology); *In re Avandia Mktg., Sales Practices & Prods. Liab. Litig.*, No. 2007-MD-1871, 2011 WL 13576, at *9 (E.D. Pa. Jan. 4, 2011) ("[The expert's] opinions expressed in this case are based on reliable scientific methodology (the review of peer-reviewed, published studies and data using well established statistical and scientific principles).").

In short, Dr. Lembke's core opinion that the increased supply and access of prescription opioids contributed to the opioid crisis is consistent with the scientific and epidemiological literature (including Dr. Lembke's own research conducted prior to this litigation), her clinical experience, and the case law.

B. Dr. Lembke's opinion that Defendants' conduct leading to the oversupply of prescription opioids caused rising rates of opioid addiction and related deaths is based on scholarly review and is generally accepted as reliable.

The only opinion contained within Dr. Lembke's report that Defendants' challenge is her opinion that opioid prescribing rates in Nassau and Suffolk Counties were likely lower in the 1990s, prior to the marketing and distribution campaigns implemented by the Defendants.[57] This opinion, however, was formed through a reliable methodology: review and assessment of relevant scientific literature and available data for the State of New York.

Dr. Lembke's opinion that Defendants' conduct collectively contributed to a paradigm shift in opioid prescribing and the oversupply of prescription opioids, which is causally related to the epidemic of opioid-induced addiction and mortality, is supported by a large body of well-accepted scientific evidence. For example, the 2017 NASEM report referenced above credited "heavy promotion of opioid prescribing by drug manufacturers (including misleading claims by some) and substantially increased prescribing" as contributors to the widespread availability and exposure to prescription opioids.[58]

Numerous additional studies in scientific journals reach similarly supportive conclusions. A 2018 article published in *Pain Physician* cited "*overwhelming evidence of misinformation and misdeeds by drug manufacturers*, drug dealers, *drug distributors*, and multiple agencies overseeing controlled substance

[57] Lembke Report, NYSCEF No. 5213, at 18.

[58] National Academies of Science Engineering and Medicine (NASEM). *Pain Management and the Opioid Epidemic: Balancing Societal and Individual Benefits and Risks of Prescription Opioid Use*; 2017. doi:10.17226/24781, at pp. 40-41 (emphasis added).

activities" among the causes of the opioid epidemic.[59] This lengthy review described the "confluence of the emergence of the influence of pharma and the death of evidence-based medicine;" the observation that "OxyContin was falsely marketed as an opioid with low addiction potential;" a "large, aggressive sales force" promoting prescription opioids; advocating the concept of "pseudo-addiction," which increased usage of opioids among patients who displayed drug-seeking behavior more indicative of addiction itself; and manipulation of State Medical Boards through industry funding of the Pain Policy Studies Group, to remove sanctions on opioid prescribing, while encouraging the concept of pain as the "5th vital sign."[60] Indeed, the authors conclude that one of the significant factors resulting in the opioid epidemic was "the influence of greed-based advocacy on the pain movement."[61] The history recounted by these independent authors in a scientific journal closely mirrors the opinion stated by Plaintiffs' expert, based on the same set of facts, and their article is among the materials relied upon by Dr. Lembke.[62]

A 2010 "Perspective" in the *New England Journal of Medicine* ("NEJM") found that "escalations" in substance abuse and mortality "parallel[ed] an increase by a factor of 10 in the medical use of opioids since 1990, spurred in part by aggressive marketing of OxyContin, an extended release form of oxycodone approved in 1995, and by efforts to encourage clinicians to become more proactive in identifying and treating chronic pain."[63] As detailed in Dr. Lembke's report, and as documented in the *Pain Physician* 2018 article (above), those efforts to encourage clinicians to be "proactive" were

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[59] Lembke Report, NYSCEF No. 5213, at Ex. B, Materials Considered #388 at 29, NYSCEF No. 5213.L. Manchikanti, *et al.*, *Reframing the Prevention Strategies of the Opioid Crisis*, 29 Pain Physician 309-326, 313 (2018) (emphasis added).

[60] *Id.* at 314.

[61] *Id.* at 322-23.

[62] Lembke Report, NYSCEF No. 5213, at Ex. B, Materials Considered #388 at 29.

[63] Lembke Report, NYSCEF No. 5213, at Ex. B, Materials Considered #472 at 35,S. Okie, *A Flood of Opioids, a Rising Tide of Deaths*, 363 New Eng. J. Med. 1981-1985, 1982 (2010) (emphasis added).

surreptitiously funded by the Defendants themselves, further supporting the causal link between Defendants' conduct, the paradigm shift in opioid prescribing, the increased supply and access of prescription opioids, and the epidemic of addiction and mortality.[64] The NEJM article further quotes an FDA Advisory panel member who stated that prescription opioids "are essentially legal heroin."[65]

A 2007 epidemiologic analysis by a CDC official concluded: "The upward trend in drug-induced mortality since 1990 is *largely due to the increasing numbers of deaths associated with prescription drugs* rather than illegal drugs. Prescription drugs now contribute to more unintentional drug-induced deaths in the US than illegal drugs. This upturn in unintentional drug deaths owes a great deal to the *dramatic increases in prescribing of, and overdoses from, opioid analgesics since 1990*."[66] The promotional materials cited in the Appendices to Dr. Lembke's Report provide additional, consistent evidence supporting her opinions, based on Defendants' internal documents that are not in the public domain and would not have been available to her previously.[67]

Defendants argue that Dr. Lembke's opinions concerning the distributors should be excluded because she did not review documents produced by those Defendants "as an example of the ways in which opioid distributors such as McKesson and opioid manufacturers such as Janssen have worked

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[64] *See* Lembke Report, NYSCEF No. 5213, at App. II, Summary of Documents from the University of Wisconsin Pain and Policy Study Group at 5, wherein Dr. Lembke summarizes the funding of such efforts by Purdue, Janssen, Endo, Ortho-McNeil, Cephalon, Alpharma, Abbott, *et al.*, concluding: "These documents provide supportive evidence for my opinion that one of the ways that the Pharmaceutical Opioid Industry created the opioid epidemic in the United States was by funding the PPSG to 'educate' the medical community as to the 'necessity' for such drugs, to influence state legislatures to increase access while loosening restrictions on prescribing, and to change the very culture of opioid prescribing, by suggesting that failing to prescribe opioids was tantamount to 'undertreating' pain and violating a patient's 'rights.'"

[65] Okie, at 1981.

[66] Lembke Report, NYSCEF No. 5213, at Ex. B, Materials Considered #488 at 36 ,L.J. Paulozzi, *et al.*, *US Data Show Sharply Rising Drug-Induced Death Rates*, 13 Injury Prevention 130-132, 130-131 (2007) (emphasis added). Paulozzi was identified in the article as affiliated with the Division of Unintentional Injury Prevention, National Center for Injury Prevention and Control, of the CDC.

[67] *See* Lembke Report, NYSCEF 5213, at Appendices I and II, providing examples of Defendants' false and misleading promotion.

in collaboration to promote opioid prescribing, contributing to the oversupply problem."[68] This argument should be rejected. In fact, the joint Distributor/Manufacturer promotional material that allowed for savings and free samples of the drugs is entirely consistent with Dr. Lembke's opinion that Defendants' conduct led to the increased supply of opioids and "[w]hen supply of that drug is increased, more people become addicted to and suffer the harms of that drug."[69]

In summary, Dr. Lembke's opinions are grounded in widespread, authoritative and peer-reviewed conclusions that Defendants' conduct resulted in the oversupply and increased access of prescription opioids, which is the root cause of the opioid epidemic.

1. The overall increased supply and access to prescription opioids throughout the country impacted Nassau and Suffolk Counties.

Dr. Lembke based her opinions about Nassau and Suffolk Counties on reliable nationwide data and extrapolation from that data. Her opinion that circumstances *throughout the United States* impacted circumstances in Nassau and Suffolk County is not baseless; rather, it is precisely the type of deduction that scientific experts engage in regularly. *See, e.g., Kurz*, 4 N.Y.S.3d at 481 (finding expert methodology appropriate where expert relied on "synthesis" of prior research lead to permissible conclusion); *Zito v. Zabarsky*, 812 N.Y.S.2d 535, 539 (2d Dep't 2006) (finding testimony admissible where expert extrapolated a theory but "set forth other scientific evidence based on accepted principles showing such a causal link"). New York courts have long recognized that "[d]eduction, extrapolation, drawing inferences from existing data, and analysis are not novel methodologies, but rather, they are accepted stages of the scientific process." *Ratner v. McNeil-PPC, Inc.*, 933 N.Y.S.2d 323, 332 (2d Dep't 2011).

[68] Presnal Aff., Ex. 10(Lembke Tr. at 258:14-18).

[69] Lembke Report, NYSCEF No. 5213, at 5-6, 99.

In her report, Dr. Lembke relies on the IQVIA data as analyzed by Plaintiffs' expert Lacey Keller and New York State Opioid Data Dashboard.[70] The data shows a drastic increase in prescribing rates in New York from 1997 to 2016—and specifically an increase in Nassau and Suffolk Counties from 2006 to 2011—including a four-fold increase in opioid mortality in the 25-44 age group from 2010 to 2016. Based on this data, and "the history of prescription opioid marketing and distribution throughout the United States," Dr. Lembke concludes that the "increase in addiction among young adults is a result of the increased supply of opioids in that community, and the increased supply is a result of defendants' actions, including distributors and pharmacies."[71]

Defendants' Memorandum significantly misconstrues the meaning of Dr. Lembke's deposition testimony concerning a patient for whom she was unable to fill a prescription for Antabuse disulfiram, an alcohol abuse drug, due to unavailability at "several different pharmacies in the area."[72] Because the drug was unavailable, an alternative medication was required to treat the patient.[73] Conversely, as Dr. Lembke testified, "every single opioid under the sun is readily available at every single pharmacy,"[74] making it a simple matter for the physician to prescribe an opioid that would be readily available to a patient at any pharmacy. Defendants' brief argues that "Dr. Lembke does not know how many doctors in Nassau and Suffolk County prescribed opioids because that doctor's preferred alternative was not available at the pharmacy,"[75] but this misses the point of her testimony: *unlike* the "unavailable" alcohol abuse medication described in her example, *prescription opioids are so*

[70] *See* Lembke Report, NYSCEF No. 5213, at 17-18, 88-89.

[71] Presnal Aff., Ex. 10 (Lembke Tr. 84:6-19); Lembke Report, NYSCEF No. 5213, at 17-18, NYSCEF No. 5213.

[72] *Id.* at. 84:21-85:11).

[73] *Id.*

[74] Presnal Aff., Ex. 10 (Lembke Tr. 85:6-9).

[75] Defs.' Lembke Brief, NY ECF No. 4348, at 10-11.

readily available that such a circumstance would rarely arise. Thus, Dr. Lembke's example illustrates precisely what the data show: oversupply and ready access to prescription opioids through the supply chain, from manufacturers to distributors, from distributors to pharmacies, and from pharmacies to patients, resulted in excess exposures, overdoses and deaths. These opinions are supported by the extensive literature cited and relied upon by Dr. Lembke in her Report.

Dr. Lembke's opinions are based on scientific evidence and research studies, supported by decades of experience treating patients and working with pharmacies to properly provide the medications she prescribes. These methods are reliable and admissible under *Frye* or any other standard.

2. *Dr. Lembke did not need to conduct or rely upon physician interviews or visits to Suffolk and Nassau county in order to render reliable opinions.*

To counter the depth of scientific literature and data supporting Dr. Lembke's opinions, Defendants seek to impose their own specific requirements on what constitutes a sufficient basis for Plaintiffs' experts' testimony. Defendants' arguments that Dr. Lembke's opinions are not reliable because she did not conduct interviews with physicians in Suffolk and Nassau Counties and did not specifically visit the counties are misplaced. Defs. Lembke Br. at 10. There is no prescribed methodology that experts must follow to develop their opinions. *Cornell v. 360 W. 51st St. Realty, Inc.*, 22 N.Y.3d 762, 780 (2014). Moreover, it is well-recognized that asking doctors individually what influenced their prescribing is unreliable. *See In re Neurontin Mktg. & Sales Practices Litig.*, 712 F.3d 21, 30 (1st Cir. 2013).[76] This is especially true in the context of controversial prescribing patterns where "self-reporting from physicians . . . shows both conscious reluctance and unconscious bias, which lead

[76] It is also axiomatic that the purpose of pharmaceutical companies' marketing initiatives is to increase prescriptions and sales. *See In re Zyprexa Prods. Liab. Litig.*, No. 04-MD-1596, 2008 WL 2696916, at *33 (E.D.N.Y. July 2, 2008), opinion clarified, No. 04-MD-1596, 2008 WL 2705475 (E.D.N.Y. July 9, 2008) ("It is undisputable that expenditures for drug marketing increase sales. The billions spent by the pharmaceutical industry attests to that. Physicians, despite what most claim, *are* influenced both consciously and unconsciously by commercial promotional messages.").

them to deny being influenced." *Id.* Aggregate data, such as the information Dr. Lembke relied upon, provides a more reliable indication than individual physician anecdotes.

Whether or not Dr. Lembke ever visited Nassau or Suffolk Counties is similarly beside the point. Defendants provide no reasoning for their suggestion that a visit to Nassau or Suffolk Counties would impact Dr. Lembke's careful and critical analysis of decades worth of data. *See* Defs. Lembke Br., NYSCEF No. 4348, at 10. Instead, Defendants mischaracterize Dr. Lembke's opinions as "impermissible speculation," pointing to *Gomez v. N.Y.C. Hous. Auth.*, 636 N.Y.S.2d 271 (1st Dep't 1995), for support. *Id.* *Gomez* is inapposite here because it addressed testimony that was inadmissible because it was "not based … on facts 'in the record or personally known to the witness.'" *Id.* at 276. In fact, in *Gomez*, the witness in question admitted that his testimony was merely "cumulative feeling" with "no factual documentation to back [it] up." *Id.* In contrast, Dr. Lembke's report reflects the wealth of data and authoritative scholarship on which she relied. Rooted in these facts, Dr. Lembke developed her opinions through accepted and well-regarded scientific methods of deduction. *See Ratner*, 933 N.Y.S.2d at 332 ("Generally, deductive reasoning or extrapolation, even in the absence of medical texts or literature that support [the expert's theory] can be admissible if it is based upon more than a mere theoretical speculation or scientific hunch.").

IV. The Court should not exclude the marketing causation opinions of epidemiologist Professor Katherine Keyes or addiction specialist Dr. Anna Lembke

Defendants separately seek to exclude so-called "marketing causation" opinions offered by Dr. Lembke and Prof. Keyes. Defendants fail, however, to identify the opinions they seek to exclude, and their arguments regarding the qualifications and methodologies used by these experts are not well-taken. Although Judge Polster did preclude Dr. Lembke and Prof. Keyes from offering specific and narrow opinions, the opinions offered in this case, and the bases for them, differ significantly from the opinions on this point that were before Judge Polster. Dr. Lembke and Prof. Keyes have

responded to the issues raised by Judge Polster and now offer opinions that are well supported and within their expertise.

A. Defendants fail to identify the opinions they seek to exclude

To begin with, Defendants do not even attempt to identify with any specificity the portions of Prof. Keyes' or Dr. Lembke's opinions they seek to exclude. Their motion refers generally to Prof. Keyes' opinions on "marketing causation," *see, e.g.*, Marketing Causation Motion at 1, but never identifies the particular opinions they seek to exclude. In the MDL, Judge Polster excluded only a single paragraph of Dr. Keyes' expert report. *See* Presnal Aff., Ex. 4, Polster Marketing Causation Ruling at 21 ("This ruling applies narrowly, only to . . . the opinion contained in the first full paragraph on page 22 of [Keyes'] Report, in which she finds that Defendants' marketing efforts caused an increase in the supply of prescription opioids.") That paragraph does not appear in Dr. Keyes' report in this litigation, having been substantially revised for the precise purpose of addressing the concerns identified by Judge Polster under the more demanding *Daubert* standards for expert testimony employed in federal court.

Defendants similarly fail to identify the particular opinions of Dr. Lembke they seek to exclude. As in Dr. Keyes' case, the MDL ruling by Judge Polster was narrow, and specifically excluded only the opinions that "(3) the Pharmaceutical Industry increased sales of prescription opioids by convincing prescribers that liberal opioid prescribing is based on science," and "(5) "the Pharmaceutical Opioid Industry's actions 'significantly influenced doctors,' and these misconceptions were the 'single most significant factor' giving rise to the massive increase in opioid sales and resulting epidemic of dependence and addiction." Polster Ruling at 9-10. As with Dr. Keyes, the opinions excluded by Judge Polster do not appear in Dr. Lembke's Report for the New York litigation, and Defendants have not identified any particular opinions that they seek to exclude. Moreover, Judge Polster specified that his ruling was "narrow," and that Dr. Lembke was fully qualified and permitted

to offer all of the other opinions in her Report, including the opinions regarding any "inaccuracy of statements and representations in Defendants' marketing materials and other promotional and/or educational efforts." Polster Ruling at 12.

Plaintiffs, much less the Court, should not be expected to guess at the expert opinions subject to Defendants' motion. Their "targeted motion" utterly fails to identify its target. For this reason alone, the motion should be denied.

B. Prof. Keyes is qualified to opine about the causal relationship between exposure to marketing and prescribing behavior.

Dr. Keyes is eminently qualified to testify that pharmaceutical "marketing of opioids to physicians that downplayed the risks of harms associated with prescribing, including opioid use disorder and overdose" increased the sales of the marketed drugs. *See* Keyes Rep., NYSCEF No. 5212, at 14. She is an epidemiologist. Epidemiology is the field of science that studies the incidence, distribution, and cause of disease in populations. Reference Manual on Scientific Evidence (3d 2011) ("RMSE") at 551; *see also* Presnal Aff., Ex. 4 at 20; Keyes Report, NYSCEF No. 5212, at 10-11. The first step in establishing causation is observing an association between a particular exposure and an increased risk of disease in a population. RMSE at 552. An association between an exposure and a disease exists when they occur together more frequently than one would expect by chance. *Id.* at 566. Once an association is established, scientists, and in particular, epidemiologists, consider whether that association reflects an actual cause-effect relationship. *See id.* at 566, 597-606. There are nine factors that epidemiologists commonly use in aid them in assessing causation: they look at the strength of the association; at the temporal relationship; whether there is a "dose-response" relationship; whether the findings have been replicated; whether a causal relationship is plausible; whether causation is consistent with other knowledge; what alternative explanations exist for the association; what happens when exposure ceases; and how specific the association is. *Id.* at 599-606. No one factor is

determinative and a judgment of causation may be reached in the absence of any or several of the factors (with the exception of temporality, because causes must precede effects). *Id.* at 599-601.

Thus, assessing whether an association found between exposure and an outcome is causal is at the heart of what epidemiologists do. The analysis is the same whether one is assessing the relationship between exposure and a disease or exposure and a behavior. As Judge Polster found, as a prominent epidemiologist, Dr. Keyes "clearly has specialized training and expertise in statistical analysis and the determination of factors that play a role in producing opioid-related harm." Presnal Aff., Ex. 4, at 20.

Moreover, again as recognized by Judge Polster, Dr. Keyes had, even before this litigation began, extensive expertise on opioid-related harm and had published nineteen peer-reviewed journal articles on the subject. *Id.* at 19. Given her background in opioids work, as well as her authorship of multiple textbooks concerning the use of statistical analyses in epidemiology and public health, she has the expertise to consider the plausibility, strength, consistency, and specificity of the association between pharmaceutical marketing and opioid use, as well as to consider and rule out alternative explanations for this association.

In the MDL, Judge Polster excluded Dr. Keyes' expert opinion on marketing causation for one exceedingly narrow reason: "her Report does not indicate that, in formulating this opinion, Keyes performed the methodology that is standard in the scientific process of her field of expertise, *i.e.*, epidemiology. In other words, Keyes has not shown that she applied epidemiological methods to determine that a cause-effect relationship may be inferred from the study that she cites." Presnal Aff., Ex. 4 at 20 (citations omitted).

Dr. Keyes directly addressed this deficiency in her report in this case:

> While I did not evaluate the specific marketing materials of the manufacturers, I did evaluate peer-reviewed epidemiological studies that document the association between marketing with sales, which is germane to my expertise. Epidemiological evidence using statistical methods is routinely used to assess the association between exposure

> to pharmaceutical marketing and sales efforts with changes in prescribing, and has reliably found across many studies in many populations that exposure to pharmaceutical marketing and sales is significantly associated with increases in prescribing of the marketed drugs. Indeed, available epidemiological evidence using rigorous quasi-experimental designs, such as difference-in-difference models, as well as controlling for numerous potential confounders, has consistently documented an association between the industry payments, meals, sales outreach to physicians, as well a[s] pharmaceutical promotions, with increases in requests to add specific products to hospital formularies as well as increases in rates of prescribing the marketed produc[t]. These broader literatures provide a consistent evidence base when examining the associations between opioid marketing and opioid sales.

Keyes Report, NYSCEF No. 5212, at 27 (citations omitted). Thus, her report in this case makes clear (as her MDL report perhaps did not) that her analysis of studies documenting a correlation between the marketing of prescription opioids and increased opioid prescriptions, and her assessment that the correlation reflects a causal relationship, directly employed the epidemiological methods in which she is an expert. There is simply no basis for this Court to find that she is not qualified to offer an expert opinion on this subject.

C. Prof. Keyes applied a generally accepted methodology in formulating her opinions about marketing and prescribing.

In reaching her conclusion concerning the causal relationship between pharmaceutical marketing and opioid abuse, Dr. Keyes employed a methodology that is generally accepted within her field of expertise. There is nothing novel or unreliable about her methods. She looked at published, peer-reviewed studies that had found this association, and assessed them for their statistical validity by employing the generally accepted methodology of her profession.

It is irrelevant that none of the studies she examined may have been directly based on the precise marketing allegations before this Court. Reliable medical and scientific literature may establish an objective basis for an expert's opinions even where such studies are not "exactly parallel to those under consideration in the litigation." *Zito v. Zabarsky*, 28 A.D.3d 42, 44, 812 N.Y.S.2d 535 (2d Dep't 2006); *Kurz v. St. Francis Hosp., Roslyn, New York*, 47 Misc. 3d 184, 193, 4 N.Y.S.3d 475, 481 (N.Y. Sup. Ct. 2014) (rejecting Frye challenge in medical malpractice case). "It is sufficient if a synthesis of various

studies or cases reasonably permits the conclusion reached by the plaintiff's expert." *Id.* That is especially the case here, where common sense (Defendants would not spend money on marketing if it did not increase sales), the Defendants' own documents concerning the return on investment of their marketing efforts,[77] and Defendants' own expert witnesses all support the same causal relationship Dr. Keyes found.[78]

Defendants' other arguments for excluding Dr. Keyes' testimony on marketing causation are irrelevant and barely worth mentioning. Defendants offer no explanation for why it should be necessary for Plaintiffs' experts to conduct their own statistical analyses of the effects of Defendants' marketing efforts. Defs. Marketing Causation Brief, NYSCEF No. 4390. at 7-9. Dr. Keyes based her opinion on this subject on her professional review of published medical and scientific literature, evaluated in accordance with generally accepted epidemiological standards; Defendants provide no grounds for this Court to conclude that this is not a legitimate basis for her expert testimony.

Similarly, Defendants fail to explain why talking to doctors or patients about the effects of pharmaceutical marketing should be necessary to expert testimony, let alone why it would provide a reliable basis for assessing a causal association. *Id.* at 10-11. *See In re Neurontin Marketing and Sales Practices Litigation*, 712 F.3d 21, 30, 45 (1st Cir. 2013) (noting unreliability of physician self-reporting with respect to influence of pharmaceutical marketing). As for Defendants' argument that Dr. Keyes

[77] TEVA_MDL_A_01543547 at 40-41 TEVA_MDL_A_01543547 at 40-41, (identifying that for the top 1,000 Fentora writers, $1,000 in promotion gets Cephalon $15,000 in Fentora prescriptions, and for the top 200 Fentora writers, $1,000 in promotions returns $32,000 in Fentora prescriptions); Exh. 130, EPI001514810 at slide 35, (finding a nearly 200% return on investment for Opana ER due to speaker programs); Exh. 132, JAN-MS-00309600 at slide 8 (detailing resulted in new prescriptions in the current period, but also in the future); Exh. 134, ALLERGAN_MDL_00450170-0193 at 0184 (finding a 15.9 to 1 return on investment).

[78] It is also worth noting that the causal standard for public nuisance liability under New York law is lower than that which was at issue in the MDL *Daubert* motions. Plaintiffs here need not establish that Defendants' conduct was the proximate cause of the public nuisance; an association between that conduct and the nuisance is sufficient to establish liability. *See* Plaintiffs' Memorandum of Law in Opposition to Defendants' Motions for Summary Judgment Regarding Proof of Causation (NYSCEF No. 3688), at pp. 7-11.

failed to consider the role of other factors on opioid prescribing, *id.* at 11-12, she directly addressed that issue in her report, explaining that:

> Key to epidemiological assessments is the concept of risk factors. Risk factors are variables that, when present, increase the frequency with which an outcome occurs, but need not be necessary or sufficient for the occurrence of the outcome to be fully determined. . . . I will apply the same "risk factor" framework to my assessment of the causes of the opioid crisis, considering factors to be causes of opioid use disorders, overdose, and related harm if some cases would not have occurred in the absence of prescription opioid use. This framework does not preclude or ignore that addiction and related harms are multi-factorial in their etiology, but rather asks whether there are cases for which the outcome would not have occurred without the presence of prescription opioid use.

Keyes Report, NYSCEF No. 5212, at 11; *see also* MDL Gateway Hypothesis Order, Ex. 3 at 14 (favorably citing this causation analysis).

At most, each of these factors pertains only to the weight the Court should give to Dr. Keyes' testimony, not to its admissibility. *Kurz v. St. Francis Hosp., Roslyn, New York*, 47 Misc. 3d at 193, 4 N.Y.S.3d at 481. They provide no basis for excluding Dr. Keyes from testifying on this subject.

D. Dr. Lembke's report in this case includes additional credentials, experience, and materials considered, none of which were before the court in the MDL.

As is true for Prof. Keyes, Defendants' attack on Dr. Lembke's "marketing causation" opinion does not take into account that the record before this Court differs significantly from that upon which Judge Polster issued the prior ruling as to the scope of Dr. Lembke's permissible opinions. The sole basis of Judge Polster's ruling with respect to Dr. Lembke was his conclusion that "Plaintiffs have not shown that Lembke is qualified to testify as an expert on marketing causation." Ex. 4 at 12. Thus, Judge Polster did not find that Dr. Lembke was *not* qualified to offer this opinion, only that Plaintiffs had failed sufficiently to demonstrate she was. Dr. Lembke's New York Report includes the following additional statement of her experience relevant to the impact of Defendants' marketing on prescribers:

> Since the 2016 publication of my book, *Drug Dealer, M.D.,* I have been invited to make presentations to doctors, legislators, and the public, regarding the *causes of the opioid epidemic* and how we can combat it. A significant portion of my work in this area consists of describing the *false and misleading messages promoted by the Pharmaceutical Opioid*

> *Industry* as detailed in this Report, including but not limited to false representations of the risk of addiction, unsupported claims of long-term efficacy for chronic pain, downplaying the risks of dependence and withdrawal, and misinforming doctors about the extent to which opioid doses could safely be increased. As to all of these subjects, it has been my experience that *audiences of professionals and lay persons alike continue to be misled by the decades-long campaign of misinformation promoted through the Industry's marketing of opioids.* "Academic detailing" is the process of providing accurate information to medical providers about the risks and benefits of a drug, to balance and re-educate after exposure to one-sided and inaccurate messaging from the detailers who have conveyed Industry messages to those providers over extended periods of time. As noted by the Report of the Association of Schools and Programs of Public Health (ASPPH), issued in November 2019, there is a need for "extensive academic detailing and counter-detailing on opioids to *correct the inaccurate and misleading claims* previously made by the companies that manufacture those drugs*, messages that continue to confuse or mislead some patients and prescribers*."[79] I began and performed my work in academic detailing before any connection or thought of involvement in litigation, and I continue in this role to counter the false and misleading marketing messages of the Pharmaceutical Opioid Industry."[80]

Plaintiffs respectfully submit that Dr. Lembke's qualifications to opine on the effects of Defendants' misleading messages are significantly and sufficiently enhanced by her experience as an educator on precisely these subjects, as described above. The importance of that experience is emphasized by the post-MDL report of the ASPPH on the impact of Defendants' misleading messages.[81] This information was not before Judge Polster. Given that Plaintiffs have *now* demonstrated that Dr. Lembke has the requisite qualification to opine about the relationship between opioid marketing and increased prescribing, Defendants' motion should be denied in its entirety.

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[79] Association of Schools and Programs of Public Health (ASPPH) Report, "Bringing Science to Bear on Opioids," 11/01/2019, at p. 21.

[80] Lembke Report, NYSCEF No. 5213, at p. 4, paragraph 22 (emphasis added).

[81] It should be noted that the ASPPH Report is also supportive of Dr. Lembke's opinion that the opioid epidemic and exponential increases in opioids have been driven by "the tremendous expansion of the supply of (high-potency as well as long-acting) prescription opioids." Lembke Report, NYSCEF No. 5213, at p. 11, quoting ASPPH Report at p. 8, fn. 11.

V. The Court should not exclude the testimony of former FDA Commissioner Dr. David Kessler.

Defendants' motion to exclude the testimony of Dr. David Kessler, a former FDA Commissioner, should also be denied.

Dr. Kessler's qualifications are beyond dispute. He obtained his medical degree from Harvard Medical School and his J.D. from the University of Chicago in 1978 and 1979, respectively.[82] After completing his residency, Dr. Kessler served as the medical director of the Hospital of the Albert Einstein College of Medicine until 1990.[83] He also taught food and drug food law at Columbia University.[84]

In 1990, he became Commissioner of the United States Food and Drug Administration ("FDA") and served in that role until 1997 during the administrations of both Presidents George H. W. Bush and Bill Clinton.[85] As Commissioner, Dr. Kessler had the ultimate responsibility for implementing and enforcing the United States Food, Drug and Cosmetic Act ("FDCA").[86] He was also responsible for overseeing the Centers for Drug Evaluation and Research, for Devices and Radiologic Health and for Biologics Evaluation and Research among others.[87] During his tenure as commissioner, Dr. Kessler created the Office of Criminal Investigation to investigate suspected criminal violations of the FDCA.[88] He worked closely with, and was ultimately responsible for, FDA's division of Drug Marketing, Advertising and Communications.[89] Between 1997 and 2007, Dr. Kessler

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[82] Kessler Report, NYSCEF No. 5215, Appendix A.

[83] *Id.*

[84] *Id.*

[85] *Id.*

[86] *Id.* at ¶ 5.

[87] *Id.*

[88] *Id.*

[89] *Id.*

served as Dean of the Schools of Medicine, first at Yale and then at University of California San Francisco; he also taught pediatrics, epidemiology and biostatistics.[90]

During his career, Dr. Kessler has testified myriad times before Congress regarding prescription drugs and promotion,[91] has been awarded numerous honors,[92] and has served on several corporate boards including as the chair of compliance.[93] Over the last 30 years, he has published over 40 articles in leading peer-reviewed medical journals regarding federal food and drug regulations, including about the federal regulation of prescription drug advertising and promotion and the effects of such promotion.[94]

Based on his extensive and broad-ranging regulatory experience, Dr. Kessler's report sets forth the relevant standards for promotion of prescription drugs under FDA regulations as well as the effects of such promotion on prescribers.[95] Then, based on a comprehensive analysis of the Manufacturer Defendants' branded and unbranded promotional activities, relevant scientific literature and FDA regulations, Dr. Kessler offers opinions that the Manufacturer Defendants deviated from FDA standards by minimizing the risks and overstating the benefits of prescription opioid drugs, and that this misleading promotion altered the practice of medicine with respect to the use of opioids in the treatment of pain. Dr. Kessler also offers opinions that Johnson & Johnson's Noramco-produced high thebaine "super poppy" served as a transformational technology that enabled the growth of branded and generic drugs made by various manufacturers in the United States for multiple decades.[96]

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[90] Report, App'x A at 1, 6.

[91] *Id.* ¶ 4.

[92] *Id.* at App'x A at 3- 6.

[93] Kessler Report, NYSCEF No. 5215, at 8.

[94] *Id.* at 20-22.

[95] *Id.* ¶¶ 13-73

[96] *Id.* ¶¶ 332-350.

This shift in the way opioids were supplied and prescribed led to an increase in the risk of opioid abuse and contributed to a public health crisis.[97] In Dr. Kessler's opinion, such serious violations of FDA regulations governing promotion of prescription opioid drugs warrant corrective marketing and medical education that disseminates truthful, non-misleading, and complete corrective messaging about the violations discussed above.[98]

A. Dr. Kessler does not offer inadmissible legal opinions.

Defendants contend that Dr. Kessler offers improper legal opinions. This argument confuses two distinct frameworks: (1) the federal regulatory framework governing drugs; and (2) state law that the jury will apply to determine liability. Here, Dr. Kessler offers opinions regarding FDA regulations governing drugs and Defendants' compliance with those regulations. He does not offer opinions about state law that the jury will apply to decide liability. The law is clear that opinions regarding highly complex regulatory frameworks such as FDA's drug regulations are proper. As the New York Court of Appeals has explained, if "the expert testimony [i]s beyond the ken of the average juror, it matters not whether the testimony related to the ultimate issue in the case." *People v. Hicks*, 2 N.Y.3d 750, 751 (2004). In 2015, the Court of Appeals reaffirmed that "[t]he guiding principle is that expert opinion is proper when it would help to clarify an issue calling for professional or technical knowledge, possessed by the expert and beyond the ken of the typical juror" and that "this principle applies to testimony regarding both the ultimate questions and those of lesser significance." *People v. Rivers*, 18 N.Y.3d 222, 228 (2011) (internal citations and quotation marks omitted).

Because the field of FDA regulation of drug promotion is highly complex, courts routinely allow qualified regulatory experts to offer testimony regarding these regulations. *E.g.*, *In re Testosterone Replacement Therapy Prod. Liab. Litig.*, 2017 WL 1836443 at *14-15 ("[t]he field of FDA regulation of

[97] *Id.* at ¶ 41

[98] *Id.* ¶¶ 67-73.

pharmaceutical products and marketing is highly complex, and a jury reasonably requires assistance to understand it . . . plaintiffs' claims are based on state law doctrines such as negligence, failure to warn . . . The ultimate conclusions a jury will have to draw are rooted in state law, not federal law.); *In re Mirena IUD Prod. Liab. Litig.*, 169 F. Supp. 3d at 467 ("Expert testimony regarding Bayer's compliance with FDA regulations therefore will not usurp the Court's role in explaining the law to the jury, but will assist the jury in determining whether Bayer acted as a reasonably prudent pharmaceutical manufacturer.") (internal quotations omitted) (citing *Wells*, 2013 WL 7208221, at *1); *In re Yasmin*, 2011 WL 6302287, at *25; *In re Fosamax Prods. Liab. Litig.*, 645 F. Supp. 2d 164 at 191 (S.D.N.Y.,2009); *see also In re Bard IVC Filters*, 2017 WL 6523833, at *8 (expert permitted to offer opinions concerning FDA regulatory process and compliance).

Experts may likewise offer opinions that embrace an ultimate issue. *See* New York Rule of Evidence 7.01(3); *see also People v. Lee*, 96 N.Y.2d 157, 162 (2001) ("Courts should be wary not to exclude such testimony merely because, to some degree, it invades the jury's province. As we have previously noted, [e]xpert opinion testimony is used in partial substitution for the jury's otherwise exclusive province which is to draw 'conclusions from the facts.' It is a kind of authorized encroachment in that respect.") (internal citation omitted).

Here, Dr. Kessler is offered to provide testimony on the federal regulatory framework for prescription drugs, marketing requirements, FDA practices and procedures, the applicable standard of care applicable to a pharmaceutical company, and Defendants' compliance with FDA regulations and industry standards, including facts from which the jury could infer knowledge and intent. Relevant, non-cumulative facts are properly relied upon by Dr. Kessler in forming his opinions.

Courts have routinely allowed Dr. Kessler to offer testimony in these areas. *See*, *e.g.*, *In re National Prescription Opiate Litig.*, 2019 WL 4165021, at *4 (N.D. Ohio Sept. 3, 2019) ("Kessler may testify as to most if not virtually all of his specific opinions with crossing [applicable] boundaries" and

denying Defendants' motion to exclude Dr. Kessler's general opinions."); *Drake v. Allergan, Inc.,* 2014 WL 5392995, at *6 (D. Vt. Oct. 23, 2014) (permitting Dr. Kessler to "testify about the FDA's regulatory scheme in general, FDA practices, and procedures, [the defendant's] compliance with FDA regulations, the FDA's relationship with pharmaceutical companies, and the standard of care for the pharmaceutical industry based on his training and experience."); *Wells v. Allergan*, 2013 WL 7208221, at *1–2 (W.D. Okla. 2013); *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 628-32 (S.D. W.Va. 2013); *Georges v. Novartis Pharm.* Corp., No. CV 06–5207 SJO (VBKx), 2012 WL 9064768, at *9-10 (C.D. Cal. Nov. 2, 2012); *In re Fosamax*, 645 F. Supp. 2d. 164, 192 (S.D.N.Y. 2009); *In re Bard IVC Filters*, 2017 WL 6523833, at *7 (D. Ariz. Dec. 21, 2017).

Defendants cite several cases in support of their argument that Dr. Kessler's regulatory opinions are improper, but none support that conclusion. Three of Defendants' citations are cases where the proposed expert opined on issues to be determined by the trial court. *See Colon v. Rent-A-Center, Inc.*, 276 A.D.2d 58, 61-62 (1st Dep't 2000) (involved contract dispute where the parties called on expert witnesses to offer opinions as to the legal obligations of parties under a contract, an issue to be determined by the trial court); *In re Prograf Antitrust Litig.*, No. 11-md-02242, 2014 WL 7641156 (D. Mass. Dec. 23, 2014) excluded opinions that a requested label change would have constituted fraud on the FDA and regarding fraud more generally, but allowed Dr. Kessler to testify about factors FDA generally takes into account in evaluating citizen petitions); *Caplan v.Winslett*, 218 A.D.2d 148, 155–56, 637 N.Y.S.2d 967 (1996) (quoting *Marx & Co. v Diners' Club*, 550 F.2d 505, 512 (2d Cir. 1988) (involved use of a purported special master on a motion to dismiss for failure to state a cause of action where the issue should have been addressed by the court itself); *Litts v. Wayne Paving Co., Inc.*, 261 A.D.2d 906, 906 (4th Dep't 1999) (expert testimony regarding interpretation of vehicle and traffic law was held improper because interpretation of vehicle and traffic law are for the court to determine).

Defendants' next citation, *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 628-29 (S. D. W.Va. 2013) is likewise unavailing. There the court concluded that Dr. Kessler *could* offer expert testimony on the regulatory framework and process, the defendant's actions taken with respect to this framework and the process and form an expert opinion that embraces an ultimate issue. The court only excluded opinions that addressed determinative legal issues, such as that the product "was not reasonably safe" or that defendant "failed to warn." *Id.* Dr. Kessler does not offer such opinions here.

Nor are Dr. Kessler's opinions likely to mislead the jury. Defendants claim that Dr. Kessler's opinions regarding FDA regulations are likely to mislead or confuse the jury and unduly prejudice Manufacturer Defendants because FDA's "false or misleading" standard does not evaluate whether a statement is actually "false" or "misleading" as those terms are commonly understood. This distinction does not lead to the conclusion that the jury will be misled.[99] At trial, Dr. Kessler will testify that to be compliant with FDA regulations, a manufacturer must have substantial scientific evidence, *e.g.*, adequate and well controlled clinical trials, to make a health claim regarding a prescription drug. *See* 21 C.F.R. § 202.1(e)(6). This standard represents FDA's considered judgment as to the evidence required to protect the public health when making a health claim about a prescription drug. Dr. Kessler's discussion and application of the substantial evidence standard does not mean that the jury will be misled. *If* Manufacturer Defendants have evidence that clinical experience or other "real world experience" supports their otherwise unsubstantiated claims, they are free to present that evidence at trial. *See People v. Carter*, 2016 WL 239708 (N.Y. Sup. Ct. Jan. 12, 2016) (evidence would not confuse the issues or mislead the jury because it will be presented by qualified experts able to explain the methodologies involved. Defendants may call his own experts to rebut the evidence or explain its

[99] Some, but not all of Dr. Kessler's opinions are based on FDA's substantial evidence standard. Many offer the opinion that the Manufacturer Defendants minimized the risks of opioids, meaning that they omitted information about the risks of opioids generally or specifically from their marketing. These opinions are not based on the substantial evidence standard. *E.g.*, Kessler Report, NYSCEF No. 5215, at ¶¶ 19, 21, 23, 24.

limitations . . . Merely invoking the word prejudice' does not, in and of itself exclude admission of relevant evidence.") (citation omitted). However, their brief cites no such evidence and Plaintiffs are unaware of any such evidence, so this argument is hypothetical at best. The four-sentence case cited by Defendants in support of their argument, *People v. Hall*, 251 A.D. 242, 243 (1st Dep't 1998), approving of the exclusion of expert testimony concerning the practices of drug dealers lacks sufficient detail to demonstrate why it is relevant to Defendants' arguments.

B. Dr. Kessler's testimony does not constitute improper factual narrative.

No more availing are Defendants' arguments that Dr. Kessler offers improper narrative opinion. Dr. Kessler will offer testimony regarding FDA regulations applicable to Defendants' opioid drugs and misleading statements in the Manufacturer Defendants' promotional materials. In arriving at these opinions, Dr. Kessler employed the same methodology he used as Commissioner—he conducted a comprehensive review of vast amounts of Defendants' documents and the scientific literature, as identified in his 142-page materials considered list. *See* Kessler Report, NYSCEF No. 5215. He then identified the most salient of those materials (a small fraction of the documents cited in his 142 pages materials considered) and discussed those documents in his report along with the relevant FDA regulations and an explanation of why Defendants' statements constituted misleading claims.

Under these circumstances, the case law is clear that there is nothing improper about an expert's discussion of the documents they relied on to reach their opinions. *See*, *e.g.*, I*n re Yasmin and Yaz Mktg., Sales Practices and Prods. Liab. Litig.*, 2011 WL 6302287, at *13 (S.D. Ill. Dec. 16, 2011) ("'[T]here is [. . .] nothing particularly unusual, or incorrect, in a procedure of letting a witness relate pertinent information in a narrative form as long as it stays within the bounds of pertinency and materiality.'") *In re Bard IVC Filters*, 2017 WL 6523833, at *8 (D. Ariz. Dec. 12, 2017) ("Furthermore, the Court notes that narrative testimony is appropriate in some circumstances.") (citing *In re Yasmin*,

2011 WL 6302287, at *13); *Wells v. Allergan, Inc.*, 2013 WL 7208337, at *3 (W.D. Okla. Feb. 4, 2013) ("To the extent the facts relied on by [expert] in forming her opinions are relevant and not cumulative, [she] may include them in her testimony.") *In re: Tylenol (Acetaminophen) Mktg., Sales Practices, & Prod. Liab. Litig.*, 2016 WL 4538621, at *8 (E.D. Pa. Aug. 31, 2016) ("A narrative may be admissible, however, if an expert's explanation of complicated facts can help a jury better understand them.*")*; *In re Testosterone Replacement Therapy Prod. Liab. Litig. Coordinated Pretrial Proceedings*, 2017 WL 1836443, at *15 (N.D. Ill. May 8, 2017) ("AbbVie contends that Dr. Kessler's testimony amounts to an improper factual narrative with a 'spin' that requires no specialized knowledge. It contends that this amounts to improper advocacy that would invade the 'fact-finding province of the jury.' The Court disagrees. Dr. Kessler's testimony will assist the jury in determining its ultimate conclusions, and it presents no danger of invading the jury's province.")

Defendants' "improper narrative" objection is more appropriately raised at trial when the context of specific documents and expert testimony are before the Court. *See*, *e.g.*, *Nunez v. New York City Health & Hosps. Corp.*, 110 A.D.3d 686, 687 (2d Dep't 2013) ("Whether evidence should be excluded as cumulative rests within the sound discretion of the trial court"). Federal courts throughout the country have declined to exclude Dr. Kessler's opinions based on the identical argument offered by Defendants here. *See*, *e.g.*, *In re National Prescription Opiate Litig.*, 2019 WL 4165021, at 3 (N.D. Ohio Sept. 3, 2019) ("The admissibility of a particular statement or opinion is dependent on the context in which it is offered and the foundation on which it is based. The Court will take these factors and the relevant law into account when ruling at trial on the admissibility of Kessler's testimony . . ."); *see also E.I. DuPont De Nemours & Co. C-8 Pers. Injury Litig.*, 345 F. Supp. 3d 920, 926-27 (S.D. Ohio 2015); *In re Actos (Pioglitazone) Prods. Liab. Litig.*, 2014 WL 120973 at *10 (W.D. La. Jan. 10, 2014) ("this Court cannot make this determination in a vacuum. Whether the actual question asked, or opinion given is framed so as to attempt to 'read Takeda's mind' and this, would be objectionable, is

a matter this Court cannot know at this juncture, and within a vacuum."); *Johnson v. Wyeth LLC*, No. CV 10-02690-PHX-FJM, 2012 WL 1204081, at *3 (D. Ariz. Apr. 11, 2012) ("Objections to narrative testimony, however, are best made at trial").

None of the seven cases Defendants cite in support of their argument stand for the proposition that it is improper for Dr. Kessler to identify relevant manufacturer documents in support of his opinions. In *Park Slope Med. & Surgical Supply, Inc. v. Progressive Ins. Co.*, 2012 NY Slip Op 50349(U), ¶ 2, 34 Misc. 3d 154(A), 154A, 950 N.Y.S.2d 609 (App. Term) (Golia, J.P., concurring) the court *reversed* a judgment barring testimony from the defendant's expert and in a concurring opinion, one of the judges stated that "medical experts at trial *should* be able to bring their expertise to bear in a manner which amounts to more than simply regurgitating those facts included in the original peer review report." That is precisely what Dr. Kessler does in his report.

Defendants' next citation is to a 111-year old case, *Ferdon v. N.Y., O. & W. R. Co.*, 131 A.D. 380, 386 (3d Dept. 1909). In *Ferdon*, the court held that testimony from witnesses "possess[ing] no scientific knowledge on the subject [of the cause of flooding of plaintiffs' land]" and whose answers "were merely the expressions of opinions and deductions from facts" "imparted no information which could not be given by a statement or narrative of facts." In contrast to that case, Dr. Kessler's analysis and opinions are based on his vast regulatory, medical and scientific knowledge. Similarly, *Highland Capital Mgmt., L.P. v. Schneider*, 379 F. Supp. 2d 461, 469 (S.D.N.Y. 2005), which Defendants' describe as "instructive" involved "a factual narrative of the case and . . . 'lay matters which a jury is capable of understanding and deciding without the expert's help." *Id.* at 469. *Cf. In re Testosterone Replacement Therapy Prod. Liab. Litig.*, 2017 WL 1836443 at *14-15 ("[t]he field of FDA regulation of pharmaceutical products and marketing is highly complex, and a jury reasonably requires assistance to understand it.").

Defendants mistakenly invoke *Wells v. Allergan, Inc.*, 2013 WL 7208221, at *2 (W.D. Okla. 2013) for the proposition that courts have excluded Dr. Kessler's testimony to prevent him from rehashing facts untethered to any admissible opinion. That proposition is inapposite here where Dr. Kessler explains relevant FDA regulations and cites documents indicative of the manufacturer's conduct with respect to those regulations in support of his opinions. Indeed, *Wells* ultimately approved of precisely the process used by Dr. Kessler here. *See id.* ("To the extent the facts relied upon Dr. Kessler in forming his opinions are relevant and not cumulative, Dr. Kessler may include them in his testimony.").[100]

C. Dr. Kessler is well-qualified to offer opinions about prescription drug promotion in the regulatory context and his opinions are reliable.

1. Dr. Kessler's work at FDA, as well as his other experience, demonstrate sufficient expertise with respect to drug marketing and promotion

Defendants next contend that despite Dr. Kessler's extensive experience with the FDCA and its implementing regulations, including those governing prescription drug marketing, and his post-FDA experience with FDA regulations, that he lacks the qualification to serve as an expert on pharmaceutical marketing. They also challenge his methodology for his opinions—offered in the context of FDA regulations—that Defendants' deviations from FDA regulations contributed to the opioid crisis because they claim his report provides no technique supporting his assertions. As

[100] Defendants' other cases are even less on point. In *Miller v. Stryker Instruments, et al.*, 2012 WL 1718825 at *12 (D. Ariz. Mar. 29, 2012), the court concluded that the expert's opinions were unhelpful to the trier of fact and did not have a coherent methodology. In contrast, Dr. Kessler's explains the applicable FDA regulations, identifies documents of paramount importance and then offers opinions supported by those documents. *In re Rezulin Prod. Liab. Litig.*, 309 F. Supp. 2d 531, 551 (S.D.N.Y. 2004) involved a proposed expert on the history of Rezulin who was proposed to recite selected regulatory events concerning Rezulin, including Advisory Committee meetings, labeling changes, "Dear Doctor" letters, and approval and withdrawal decisions by regulators in the United States and abroad along with a "historical commentary of what happened." Dr. Kessler's opinions, in contrast, offer regulatory analysis. *In re Hogan v. Novartis Pharm. Corp.*, 2011 WL 1533467, at *8 (E.D.N.Y. Apr. 24, 2011), an epidemiology expert, was permitted to offer a number of opinions based on a methodology the court deemed reliable but was precluded from offering opinions on a critical question in the litigation based on a graph and footnote in a letter to the editor of a medical journal. In contrast, Dr. Kessler's opinions are well supported by ample evidence from the Defendants' internal files.

permitted under New York law, Dr. Kessler's opinions are based on his extensive experience and training in the field of FDA regulations and his review of scientific literature and Defendants' own documents, and are admissible.

Defendants contend that Dr. Kessler is not qualified to offer opinions about the effects of their departures from compliance with FDA's prescription drug promotion regulations because he lacks the "skill, training, education, knowledge or experience" to opine on those questions. In particular, Defendants claim that he has no experience with marketing as a general matter or in the prescription drug context. Defendants are wrong.

Under New York law, an expert may be qualified "by knowledge, skill, experience, training or education." New York Rule of Evidence 7.01(1). Dr. Kessler's extensive experience, training and education render him eminently qualified to testify regarding pharmaceutical drug promotion and its effects. As discussed above, Dr. Kessler is a medical doctor who ran a hospital in New York City for more than a decade with experience prescribing drugs and overseeing doctors who prescribed drugs. Kessler Report, NYSCEF No. 5215, App'x A at 1, Presnal Aff., Ex. 11, Kessler Tr. 326:9-12. Dr. Kessler was also commissioner of the FDA, a position that involved regulating drug manufacturers' prescription drug marketing. Dr. Kessler also worked closely with FDA's Division of Drug Promotion, DDMAC. Dr. Kessler's close involvement with DDMAC is well known including by the Manufacturer Defendants' own regulatory experts. During his tenure at FDA, Dr. Kessler also authored and signed FDA regulations governing tobacco advertising marketing.[101]

Prior to FDA, Dr. Kessler taught food and drug law at Columbia University.[102] Dr. Kessler has also published articles on the effects of inappropriate drug promotion on physician prescribing

[101] *See Kessler, David A et al.,* "The Food and Drug Administration's Regulation of Tobacco Products," New England J. Med., 335: 988-994 (1996); 61 F.R. 168 (1996).

[102] Kessler Report, NYSCEF No. 5215, at 4.

habits in prestigious medical journals such as the New England Journal of Medicine and the Journal. For example, in "Therapeutic-Class Wars—Drug Promotion in a Competitive Marketplace" published in *The New England Journal of Medicine*, Dr. Kessler explained:

> The preponderance of 'me too' drugs has created a highly competitive marketplace for prescription drugs. Pharmaceutical companies are waging aggressive campaigns to change prescribers' habits and to distinguish their products from competing ones, even when their products are virtually indistinguishable . . . Victory in these therapeutic class wars can mean millions of dollars for a drug company. But for patients and provided it can mean *misleading promotion*, conflicts of interest, increased costs for healthcare, *and ultimately inappropriate prescribing*."[103]

Dr. Kessler has served as a board member and advisor to pharmaceutical companies and private equity firms that own pharmaceutical companies. *Id.* at ¶ 6. In these capacities, he advises them on the standards and duties of care applicable to a pharmaceutical company and compliance with FDA regulations and requirements including those governing prescription drug promotion. *Id.*

Dr. Kessler's broad-ranging and multi-disciplinary training and experience in the regulation of prescription drugs, his study and teaching of those regulations, his practice of medicine, including with the prescription of drugs and oversight of the prescription of drugs, equips him with abundant "specialized knowledge" regarding prescription drug marketing and the effects of deviating from the regulations governing prescription drug marketing. The concerns raised in Defendants' cited cases are thus non-existent here. *E.g.*, *In re Nat'l Prescription Opiate Litig.*, 2019 WL 4054998, at *6 (N.D. Ohio Aug. 28, 2019) ("Plaintiffs point to no specialized training or experience by Lembke in the field of pharmaceutical marketing and/or its effect on prescribing practices"); *Pfizer v. Teva Pharmaceuticals USA, Inc.*, 461 F. Supp. 2d 271, 276 (D.N.J. 2006) (rheumatologist clearly qualified in his field of medicine, but lacked specialized expertise regarding sales of market analysis); *Hernandez v. Lutheran*

[103] Kessler, David (1994), Therapeutic-Class Wars—Drug Promotion in a Competitive Marketplace *The New England Journal of Medicine*, 331 (20), 1350-53) (emphasis added).

Med. Ctr., 46 A.D. 3d 517, 518 (2d Dep't 2007) (physicist who studied growth patterns of breast cancer in general unqualified to render expert testimony regarding retroperitoneal sarcoma tumor growth).

Based on these extensive credentials, courts have rejected identical arguments by other pharmaceutical manufacturers that Dr. Kessler is not qualified to offer opinions on their marketing practices. As the Court in *In re Testosterone Replacement Therapy Prod. Liab. Litig.,* explained:

> Dr. Kessler is amply qualified to offer his opinions on [drug company's] marketing of [prescription drug], including whether it marketed and promoted the drug for non-indicated, off-label uses. Dr. Kessler is a former Commissioner of the FDA, a position that involved the regulation of marketing by drug manufacturers, he has taught food and drug law; he has testified before Congress on food, drug, and consumer protection issues . . . He is certainly qualified to render opinions regarding whether a drug manufacturer is marketing its production for off-label uses.

Id. at *14. Plaintiffs respectfully submit that this Court should similarly reject Defendants' unsubstantiated claims and hold that Dr. Kessler's extensive qualification render him amply qualified to testify about the Manufacturer Defendants' drug promotion and its effects.

2. Dr. Kessler's methodology is not a novel scientific technique and provides a sufficient foundation for his opinion

Defendants also attack Dr. Kessler's methodology with respect to his opinion that the Manufacturers' misleading marketing contributed to opioid abuse and a public health crisis. This opinion is well grounded in published studies that demonstrate the relationship between the quantity of opioids shipped and opioid abuse.[104] Defendants ignore this foundation, and argue that Dr. Kessler has *no* methodology to support his opinion. A review of Dr. Kessler's report demonstrates otherwise.

To begin with, however, no particular "methodology" is required when an expert relies on his experience and training. *See Doviak v. Finkelstein & Partners, LLP*, 137 A.D.3d 843, 847 (2d Dep't 2016) ("[A]n expert opinion based on personal training and experience is not subject to a Frye analysis."); *see also People v. Oddone*, 22 N.Y.3d 369, 376 (2013) (evidence based on personal experience is not barred

[104] Presnal Aff., Ex. 11, MDL Deposition of David Kessler Apr. 26, 2019 Dep. Tr. 516:3-22.

by Frye in criminal case); *Board of Managers of 195 Hudson Street Condominium v. 195 Hudson Street Associates, LLC*, 63 A.D.3d 523 (1st Dep't 2009) (expert witness's education, training and experience qualified him to testify as an expert in connection with estimating costs).

Dr. Kessler's opinions about the effect of Defendants' deviation from FDA regulations governing promotion were formed through his experience as a physician, his review of studies regarding the effect of promotional activities on prescribers including the effect of inappropriate marketing of drugs with addictive properties,[105] his review of Defendants' marketing plans indicating a strategy to deviate from FDA regulations,[106] their branded and unbranded promotional materials implementing a strategy to deviate from FDA regulations,[107] Defendants' deposition testimony and internal documents about the effects of their promotion including their return on investment,[108] and scientific literature, data and deposition discussing the effects of marketing opioids through the lens of his decades of experience with the federal regulation of prescription drugs and as a physician.

Among the peer-reviewed scientific literature reviewed by Dr. Kessler was a 2006 study in *Drug and Alcohol Dependence* authored by former Purdue Pharma scientist, Curtis Wright, which examined the relationships between prescriptive usage of opioids and reported deaths at the national level based on Drug Abuse Warning Network (DAWN) data. The article stated: "[t]he conclusions reached in this study are that non-medical use of opioids is a predictable parallel phenomenon of their

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[105] *E.g.*, Kessler Report, , NYSCEF No. 5215, at ¶ 42-44 (discussing the effect of drug promotion on prescribers behavior as noted by the World Health Organization) ¶¶ 63-66 (discussing effect of non-conformance with FDA requirements on marketing and promotion on consumers)

[106] *E.g.*, *id at* ¶ 382.1 ("ROI for [Opana ER] stated: Potential sales of [Opana ER] depend directly on prescribers' comfort level with risk of abuse and diversion)

[107] *E.g.*, *id at* ¶ 387.7 ("Endo's market research from 2008 show that 'Low Abuse Potential' was the primary factor influencing physician' anticipated increase in use of Opana ER."), ¶ 390.1 (2009 Opana ER "Instant Savings" card minimized the risk of addiction); ¶¶ 394.1-394.2 ("Despite lack of substantial evidence for the concept of pseudoaddiction, Endo included the term in its sales training materials for Opana ER")

[108] *E.g.*, *id at*¶ 390.1, n. 739 (2010 Oxymorphone Franchise Tactical Plan for Opana Brand reported that Opana Instant Savings Program had a 14% redemption rate in 2009 for a total of 58, 227 redemptions.

prescriptive availability and that the extent of diversion is well predicted by their relative potency of the drug and the amount in prescriptive use."[109] Dr. Kessler also reviewed a 2019 article published in the *Journal of America Medical Association* that examined to what extent the pharmaceutical industry's marketing of opioids to physicians is associated with death from prescription opioid overdoses. That article concluded that based upon a study across U.S. counties, "marketing of opioid products to physicians was associated with increased opioid prescribing and, subsequently, with elevated mortality from overdoses."[110] This evidence, and Dr. Kessler's review of it, support his opinions that Defendants' marketing of opioids was false and misleading, that it had the effect of changing the practice of medicine, and that contributed to a public health crisis.[111]

Defendants' other criticisms fare no better. They note that Dr. Kessler did not determine whether particular prescribers were misled by any Manufacturers' marketing. This ignores the body of literature cited in Dr. Kessler's report discussing the strong influence that drug promotion has on prescribing behavior including doctors' underestimation of this influence.[112] Defendants similarly fault Dr. Kessler for not determining whether any patients who received an unnecessary opioid prescription later abused the medication, became addicted to it, or diverted it. But this is beside the point. As Dr. Lembke explains in her report, "[e]ven when being prescribed by a doctor for a legitimate pain condition, opioid painkillers are as addictive as heroin purchased on a street corner, because the prescription opioids have the same addictive effects on the neurocircuitry of the brain" and "the best evidence available shows that the risk of addiction in patients taking opioids for chronic pain is

[109] N. Dasgupta, E.D. Kramer, et al., Association between non-medical and prescriptive usage of opioids, *Drug and Alcohol Dependence* 82 (2006) 135-42.

[110] Hadland et al., Association of Pharmaceutical Industry Marketing of Opioid Products With Mortality From Opioid-Related Overdoses. JAMA Netw Open. 2:e186007.

[111] Kessler Report, NYSCEF No. 5215, Conclusions ¶ 14, 41.

[112] *Id.* at ¶¶ 42-45.

between 10% and 30%." Lembke Report, NYSCEF No. 5213, at 45, 58. Given that Defendants' marketing was intended to – and Dr. Keyes, Dr. Lembke, and Dr. Kessler all opine in fact did – increase the number of opioid prescriptions, it was not necessary for Dr. Kessler to identify particular patients who abused or diverted their opioid medications, or became addicted to them.

D. Dr. Kessler's opinions about Tasmanian Alkaloids and Noramco are based on admissions about the role of the "super poppy" in Janssen's own documents and do not require more DEA experience than he has

Last, Defendants take issue with Dr. Kessler's opinions that supply of "super poppy" by Janssen subsidiaries Noramco and Tasmanian Alkaloids enabled the growth of branded and generic opioid drugs, most notably OxyContin/oxycodone, in the United States for decades. Defendants argue that these opinions should be excluded because Dr. Kessler lacks expertise with DEA's regulations and because he did not independently verify the accuracy of the Janssen documents that he relied on in support of this opinion. Both arguments are flawed.

First, Defendants' argument misstates Dr. Kessler's opinion regarding the role of Noramco's "super poppy." Dr. Kessler does not offer the opinion that Noramco's supply of its "super poppy" to various opioids manufacturer violated DEA regulations. He opines that regardless of whether Defendants complied with DEA regulations governing raw materials and API, the "super poppy" ultimately enabled increased amounts of oxycodone to be sold to opioid manufacturers. Based on these admissions, Dr. Kessler's opines that this increase in the amount of oxycodone sold to opioid manufacturers contributed to the opioid crisis. Defendants' argument that Dr. Kessler lacks experience with DEA regulations governing NRM or API is thus unavailing. In addition, Defendants omit from their brief Dr. Kessler's testimony about his expertise with FDA-DEA interactions. Dr. Kessler testified that "there may be some basic DEA questions that are within [his] purview" based on his experience as commissioner." Presnal Aff., Ex. 11, Kessler Dep. 104:22-105:20. His opinions

are well supported by Defendants' own documents[113] and do not require independent training or experience with DEA regulations.

Second, Defendants' argument that Dr. Kessler's opinion should be excluded because he did not independently verify Janssen's admissions regarding the role of the super poppy is likewise meritless. Dr. Kessler's opinions are based on admissions in Janssen's documents regarding the impact of Noramco's "super poppy" on the supply of oxycodone and need not be independently verified by him. Defendants' identify no legal requirement that Dr. Kessler do so and Plaintiffs are unaware of any.

VI. The Court should not exclude the testimony of Suffolk County's Commissioner of Health, Dr. Tomarken

Defendants also seek to exclude opinions from Dr. James Tomarken, Suffolk County's Commissioner of Health. Plaintiffs identified Dr. Tomarken as both a fact witness and a non-retained expert witness, because, in the course of his responsibilities as Health Commissioner Dr. Tomarken has formed opinions that Plaintiffs intend to offer at trial. Based on his training and experience, and, in particular, on his experience as Suffolk County Health Commissioner, Dr. Tomarken will offer opinions about the nature of the opioid crisis on Long Island; the progress of that crisis over time; the phases of the crisis as he observed them (progressing from a crisis involving prescription drugs to one involving heroin, and then to one involving fentanyl); the nature of addition; and the effects of the crisis on public health on Long Island.

Defendants seek to exclude his testimony as it was described in Plaintiffs' expert disclosure, although the opinions Dr. Tomarken intends to offer are those offered at his deposition. The motion

[113] *See, e.g.,* Kessler Report, , NYSCEF No. 5215, ¶ 339 & JAN-MS-00725219 at 6 (2003 Noramco document stating "Tasmanian Alkaloids Leads the World in Poppy Technology" noting "Patented, high thebaine poppy was a transformational technology that enabled the growth of oxycodone."); *id.* at ¶ 340.

should be denied and Dr. Tomarken should be permitted to offer all of the testimony he gave at his deposition.

A. Dr. Tomarken is qualified to offer his opinions

For the last decade, Dr. Tomarken served as the Commissioner of Health for the Suffolk County Department of Health Services. Presnal Aff., Ex. 12, at Exhibit B (Dr. Tomarken's CV). In that capacity, he was responsible for identifying and understanding issues that affect the public health and for developing public health programs to address those public health issues. To do so, he reviewed and interpreted various national, regional and local data sources, and he relied on his degrees in Doctorate of Medicine, Masters of Public Health, and Masters of Social Work, along with his training including his residency and research at the Addiction Research Foundation of Ontario. *Id.* Moreover, Dr. Tomarken relied on his work experience in the public health and medical fields, including the multiple years he served within the United States as a medical director at various health companies and served internationally leading public health initiatives. *Id.* It is his ability to identify, understand, and respond to various public health problems as a practitioner in the public health field and his specific knowledge and experience in Suffolk County that qualifies him to opine regarding the opioid crisis including its evolution and effect on the public health of Suffolk County.

Challenging his qualifications, Defendants make much of the fact that Dr. Tomarken declined to describe himself as an "expert." But that is irrelevant to whether he has the "requisite skill, training, education, knowledge or experience," *see Matott v. Ward*, 48 N.Y.2d at 459, to offer opinion testimony. Dr. Tomarken's degrees in medicine, public health, and social work, his training and research at the Addiction Research Foundation, as well as tenure as Suffolk County Health Commissioner during the opioid crisis more than qualify him to offer his opinions and observations about that crisis. Indeed, Dr. Tomarken made clear that his refusal at his deposition to claim the title "expert" was not based on any lack of knowledge, experience, or expertise, but rather on his unfamiliarity with the meaning

of the term as defense counsel used it: "I don't think I have any expertise, *because I don't know what the definition of what a medical expert is.*" Presnal Aff., Ex. 13, Tomarken Dep. at 26:24-27:1 (emphasis added). Dr. Tomarken's modesty and his refusal to claim a title without knowing its definition in no way call into question his qualifications to offer testimony in the areas of medicine, public health, and addiction.

Defendants' arguments that Dr. Tomarken lacks expertise specifically in epidemiology or addiction are readily disposed of. As the top public health official in Suffolk County, Dr. Tomarken is certainly qualified to opine about the "science of understanding the causes and distributions of population health," *see* Keyes Rep., NYSCEF No. 5212, at 10;[114] his degree in Public Health further demonstrates his experience in this field. Moreover, it is Defendants, not Dr. Tomarken, who characterize his opinions as involving "epidemiology." As the person responsible for addressing the opioid crisis in Suffolk County, Dr. Tomarken is qualified to offer opinions about the patterns and effects of opioid use on Long Island, regardless of what medical specialty Defendants decide to classify that knowledge as relating to.

Defendants' attacks on Dr. Tomarken's qualifications with respect to addiction are similarly without merit. Dr. Tomarken trained at the Addiction Research Foundation of Ontario, and has ten years of experience responding to the opioid crisis in Suffolk County. Defendants' arguments – that his training was too long ago, that it was not specific enough, or that he has not published in the field – go to the weight, not the admissibility, of his testimony, as there can be no doubt that Dr. Tomarken

[114] Dr. Keyes, who holds a Ph.D in epidemiology, further explains that "epidemiologists examine . . . how health and disease arises within [populations], as well as the conditions that shape population health over time and space, including policies, practices, and politics that create conditions that improve or deteriorate population health." Keyes Rep., NYSCEF No. 5212, at 10. In his role as Commissioner of Public Health, it is clear that Dr. Tomarken's job calls for him to practice epidemiology every day, whether or not he is willing to claim expertise in that field.

is qualified by reason of his training at the Addiction Research Foundation to offer opinions about addition medicine. *See Adamy,* 92 N.Y.2d at 402; *Leavy*, 133 A.D.3d at 638.

B. Dr. Tomarken was not required to provide a report and may offer at trial all of the information to which he testified at his deposition

Defendants seek to preclude Dr. Tomarken from offering opinions as described in Plaintiffs' December 19, 2019 expert disclosures. But those disclosures do not define the scope of Dr. Tomarken's opinions. Rather, the opinions he intends to offer are those to which he testified at his deposition. Dr. Tomarken's expected testimony was summarized in advance of the deposition by Plaintiffs in order to provide Defendants with even greater disclosure than is required under the Commercial Division Rules, but the summaries offered by Plaintiffs do not limit or define the opinions to be offered at trial.

Rule 13(c) of the Commercial Division Rules provides for "expert disclosure – including the identification of experts, exchange of reports, and depositions of testifying experts. . . ." The rule further provides that "expert disclosure must be accompanied by a written report, prepared and signed by the witness, *if* either (1) the witness is retained or specially employed to provide expert testimony in the case, or (2) the witness is a party's employee whose duties regularly involve giving expert testimony." Rule 13(c) (emphasis added). Because Dr. Tomarken was not retained or specially employed to provide expert testimony, and because his duties as Suffolk County Health Commissioner do not regularly involve giving expert testimony, *see* NYSCEF Doc. No. 3160, Dr. Tomarken was not required to "prepare[] and sign[]" an expert report. Rule 13 thus required only that *Plaintiffs* identify Dr. Tomarken as an expert witness, and to offer him for deposition.

Plaintiffs went beyond what was required of them. Rather than simply provide Dr. Tomarken's name and title, as Rule 13(c) plainly allowed them to do, Plaintiffs provided a description of the opinions they expected Dr. Tomarken to offer. *See* Presnal Aff., Ex. 13. Defendants make much of the fact that Dr. Tomarken did not review this disclosure, but there was no need for him to

do so. The disclosure was not his, and was not an expert report; it was Plaintiffs' good-faith attempt provide Defendants with additional information about Dr. Tomarken's expected testimony.

Defendants address their motion to the information disclosed by Plaintiffs, but Dr. Tomarken's testimony is not limited in any way by that disclosure. As noted, Plaintiffs were not required to disclose Dr. Tomarken's opinions at any time. (This contrasts sharply with the rule applicable to *reporting* experts, which requires an expert to provide, *inter alia,* "a complete statement of all opinions the witness will express and the basis and the reasons for them . . . ."). Defendants were entitled, and had the opportunity, to ask Dr. Tomarken at his deposition what opinions he plans to offer and otherwise to elicit testimony, both opinion and factual, that Dr. Tomarken expects to offer at trial. Indeed, Defendants examined Dr. Tomarken at length; his deposition commenced shortly after 9 a.m. on January 30, 2020, and concluded after 5:30 p.m. Yet Defendants do not seek to exclude *any* of the testimony offered at that deposition. Dr. Tomarken should be permitted to offer at trial all of the testimony he gave at his deposition.

C. Dr. Tomarken may give causation or "gateway opinions"

Defendants argue that Dr. Tomarken may not testify that prescription drug use and misuse led to and caused increases in heroin and fentanyl use, contending that he disclaimed such opinions at his deposition and that the data on which he relied is unreliable. Neither argument has merit.

Defendants take isolated remarks from Dr. Tomarken's deposition in order to suggest that Dr. Tomarken has no opinion about the connection between prescription drug use and the increases in heroin and fentanyl use later observed in Suffolk County. Nothing could be further from the truth. At his deposition, Dr. Tomarken specifically adopted and endorsed the statement that "[t]he first phase of the opioid epidemic involving primarily prescription opioids contributed to causing the rise in heroin-related problems in the second phase because, as it became more difficult to obtain prescription opioids, persons with opioid use disorder turned to less expensive and more readily

available sources of opioids, such as heroin." Presnal Aff., Ex 14, Tr. at 51:5-22 (Q: "Does paragraph C accurately reflect the opinions that will provide in this case? A. Yes."). The causation issue as to which he disclaimed an opinion was the general question "what has caused opioid-class drugs to be a drug of abuse in Suffolk County." *Id.* at Tr. 147:23-148:2. That Dr. Tomarken has no view about the underlying cause of the abuse of opioid drugs generally, including, in particular, prescription opioids, in no way undermines, much less disclaims, a view about how the use of prescription opioids caused increases in heroin and fentanyl use and abuse. Nor does Dr. Tomarken's inability to quantify the precise percentage of heroin-related problems that were caused by problems with prescription opioids provide a basis to exclude his opinion that the first phase of the crisis – prescription drug use – caused and contributed to the second phrase, involving heroin use. His opinion is that the first phase "contributed" to the second phase – that opinion is proper and has a sufficient foundation regardless of whether he can put a percentage on the extent of the contribution.

Defendants' attack on the data Dr. Tomarken used to form his opinion is similarly unavailing. To begin with, Defendants question only one of the multiple data sources Dr. Tomarken relied on. They do not mention – let alone challenge – the multitude of other credible data sources upon which Dr. Tomarken relies. For instance, Dr. Tomarken reviewed and relied upon national and regional data from the Center for Disease Control ("CDC"), *see* Presnal Aff., Ex 14, Tr. 328:24-330:10, New York State Department of Health, *id.* at Tr. 330:24-331:7, National Institute of Drug Abuse ("NIDA"), *id.* at Tr. 331:8-331:24) and SAMSHA, *id.* at Tr. 332:11-333:4. Thus, Dr. Tomarken's opinions have more than sufficient scientific support as required by the *Frye* standard. *Lugo,* 89 A.D.3d at 56. Curiously, the data they *do* question is data that Dr. Tomarken received from Dr. Michael Caplan, the Suffolk County Medical Examiner – but Defendants have not sought to exclude the same opinion offered by Dr. Caplan based on the same data. Moreover, Dr. Tomarken may rely on information from another expert, so long as that expert is also subject to cross-examination. *See Natale v. Niagara*

Mohawk Power Corp., 135 A.D.2d 955, 957 (3d Dept. 1987) ("it is also acceptable for an expert, in forming a professional opinion, to base it on information coming from a witness subject to full cross-examination . . . "); *Rodolitz v. Bos.-Old Colony Ins. Co.*, 74 A.D.2d 821, 821 (2d Dept. 1980) ("expert may base his opinion upon facts proven by, or reasonably inferrable from, the testimony of other witnesses"); *see also O'Shea v. Sarro*, 106 A.D.2d 435, 437 (1984). Here, Dr. Caplan has also been designated as an expert by the Plaintiffs, Defendants have taken his deposition and fully examined him, and have not sought to exclude his testimony. Moreover, Dr. Caplan's deposition shows that his data is grounded in his research into various sources including the CDC and the PubMed research database. Presnal Aff., Ex 14 (Caplan Dep, February 20, 2020), at 441:9-20, 444:10-20.

D. Dr. Tomarken's opinion that there is an opioid crisis on Long Island and that it interferes with public health is not an impermissible legal conclusion

Defendants also seek to preclude Dr. Tomarken from testifying that there is an opioid crisis on Long Island, and that it interferes with public health. This is not an impermissible legal conclusion. Dr. Tomarken does not purport to offer an opinion on the *legal* question as to whether the opioid crisis constitutes a public nuisance, but it would be shocking indeed if the top public health official in Suffolk County could not offer the opinion that the crisis he is combatting has affected the public health he is charged with protecting. Nor does the law prevent him from doing so. As noted above, experts may offer opinions related to the ultimate issue in a case. *See Hicks*, 2 N.Y.3d at 751; *Rivers*, 18 N.Y.3d at 228. As discussed above, the cases cited by Defendants do not hold otherwise.

CONCLUSION

For the reasons stated, Defendants' motions to exclude the testimony of Plaintiffs' experts should be denied.

Dated: March 10, 2020

Respectfully submitted,

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